Title 21 —Food and Drugs
Chapter I —Food and Drug Administration, Department of Health and Human Services
Subchapter H —Medical Devices

PART 870—CARDIOVASCULAR DEVICES

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Source: 45 FR 7907, Feb. 5, 1980, unless otherwise noted.

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Subpart A—General Provisions

§ 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*..

[52 FR 17735, May 11, 1987, as amended at 68 FR 61344, Oct. 28, 2003; 78 FR 18233, Mar. 26, 2013]

§ 870.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a “new” device as defined in this section because of any new intended use or other reasons, FDA may

codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17735, May 11, 1987]

§ 870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2314, Jan. 14, 2000]

Subpart B—Cardiovascular Diagnostic Devices

§ 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

(a) ***Identification.*** The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.

(b) ***Classification.*** Class II (special controls). The guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" will serve as the special control. See § 870.1 for the availability of this guidance document.

[68 FR 61344, Oct. 28, 2003]

§ 870.1100 Blood pressure alarm.

(a) ***Identification.*** A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a pre-set upper or lower limit.

(b) ***Classification.*** Class II (performance standards).

§ 870.1110 Blood pressure computer.

(a) ***Identification.*** A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

(b) ***Classification.*** Class II (performance standards).

§ 870.1120 Blood pressure cuff.

(a) ***Identification.*** A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

(b) ***Classification.*** Class II (performance standards).

§ 870.1130 Noninvasive blood pressure measurement system.

(a) ***Identification.*** A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of tranducers placed on the surface of the body.

(b) ***Classification.*** Class II (performance standards).

§ 870.1140 Venous blood pressure manometer.

(a) ***Identification.*** A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

(b) ***Classification.*** Class II (performance standards).

§ 870.1200 Diagnostic intravascular catheter.

(a) ***Identification.*** An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

(b) ***Classification.*** Class II (performance standards).

§ 870.1210 Continuous flush catheter.

(a) ***Identification.*** A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.

(b) ***Classification.*** Class II (performance standards).

§ 870.1220 Electrode recording catheter or electrode recording probe.

(a) ***Identification.*** An electrode recording catheter or an electrode recording probe is a device used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum-tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.

(b) ***Classification.*** Class II (performance standards).

§ 870.1230 Fiberoptic oximeter catheter.

(a) ***Identification.*** A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

(b) ***Classification.*** Class II (performance standards).

§ 870.1240 Flow-directed catheter.

(a) ***Identification.*** A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.

(b) ***Classification.*** Class II (performance standards).

§ 870.1250 Percutaneous catheter.

(a) ***Identification.*** A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

(b) ***Classification.*** Class II (performance standards).

§ 870.1251 Temporary catheter for embolic protection during transcatheter intracardiac procedures.

(a) ***Identification.*** This device is a single use percutaneous catheter system that has (a) blood filter(s) at the distal end. This device is indicated for use while performing transcatheter intracardiac procedures. The device is used to filter blood in a manner that may prevent embolic material (thrombus/debris) from the transcatheter intracardiac procedure from traveling towards the cerebral circulation.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Simulated-use testing in a clinically relevant bench anatomic model to assess the following:

(A) Delivery, deployment, and retrieval, including quantifying deployment and retrieval forces, and procedural time; and

(B) Device compatibility and lack of interference with the transcatheter intracardiac procedure and device.

(ii) Tensile strengths of joints and components, tip flexibility, torque strength, torque response, and kink resistance.

(iii) Flow characteristics.

(A) The ability of the filter to not impede blood flow.

(B) The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow.

(iv) Characterization and verification of all dimensions.

(2) Animal testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed:

(i) Delivery, deployment, and retrieval, including quantifying procedural time.

(ii) Device compatibility and lack of interference with the transcatheter intracardiac procedure and device.

(iii) Flow characteristics.

(A) The ability of the filter to not impede blood flow.

(B) The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow.

(iv) Gross pathology and histopathology assessing vascular injury and downstream embolization.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Labeling for the device must include:

(i) Instructions for use;

(ii) Compatible transcatheter intracardiac procedure devices;

(iii) A detailed summary of the clinical testing conducted; and

(iv) A shelf life and storage conditions.

(7) Clinical performance testing must demonstrate:

(i) The ability to safely deliver, deploy, and remove the device;

(ii) The ability of the device to filter embolic material while not impeding blood flow;

(iii) Secure positioning and stability of the position throughout the transcatheter intracardiac procedure; and

(iv) Evaluation of all adverse events including death, stroke, and vascular injury.

[83 FR 4140, Jan. 30, 2018]

§ 870.1252 Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access.

(a) ***Identification.*** This device is a single use percutaneous catheter system that creates an arteriovenous fistula in the arm of patients with chronic kidney disease who need hemodialysis.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate:

(i) The ability to safely deliver, deploy, and remove the device;

(ii) The ability of the device to create an arteriovenous fistula;

(iii) The ability of the arteriovenous fistula to attain a blood flow rate and diameter suitable for hemodialysis;

(iv) The ability of the fistula to be used for vascular access for hemodialysis;

(v) The patency of the fistula; and

(vi) The rates and types of all adverse events.

(2) Animal testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed:

(i) Delivery, deployment, and retrieval of the device;

(ii) Compatibility with other devices labeled for use with the device;

(iii) Patency of the fistula;

(iv) Characterization of blood flow at the time of the fistula creation procedure and at chronic followup; and

(v) Gross pathology and histopathology assessing vascular injury and downstream embolization.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Simulated-use testing in a clinically relevant bench anatomic model to assess the delivery, deployment, activation, and retrieval of the device;

(ii) Tensile strengths of joints and components;

(iii) Accurate positioning and alignment of the device to achieve fistula creation; and

(iv) Characterization and verification of all dimensions.

(4) Electrical performance, electrical safety, and electromagnetic compatibility (EMC) testing must be performed for devices with electrical components.

(5) Software verification, validation, and hazard analysis must be performed for devices that use software.

(6) All patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(8) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(9) Labeling for the device must include:

(i) Instructions for use;

(ii) Identification of system components and compatible devices;

(iii) Expertise needed for the safe use of the device;

(iv) A detailed summary of the clinical testing conducted and the patient population studied; and

(v) A shelf life and storage conditions.

[87 FR 9241, Feb. 18, 2022]

§ 870.1255 Balloon aortic valvuloplasty catheter.

(a) ***Identification.*** A balloon aortic valvuloplasty catheter is a catheter with a balloon at the distal end of the shaft, which is intended to treat stenosis in the aortic valve when the balloon is expanded.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible.

(2) Sterility and shelf life testing must demonstrate the sterility of patient-contacting components and the shelf life of these components.

(3) Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use, including device delivery, inflation, deflation, and removal.

(4) In vivo evaluation of the device must demonstrate device performance, including the ability of the device to treat aortic stenosis.

(5) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device.

[82 FR 34852, July 27, 2017]

§ 870.1270 Intracavitary phonocatheter system.

(a) ***Identification.*** An intracavitary phonocatheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.

(b) ***Classification.*** Class II (performance standards).

§ 870.1280 Steerable catheter.

(a) ***Identification.*** A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.

(b) ***Classification.*** Class II (performance standards).

§ 870.1290 Steerable catheter control system.

(a) ***Identification.*** A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

(b) ***Classification.*** Class II (performance standards).

§ 870.1300 Catheter cannula.

(a) ***Identification.*** A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.

(b) ***Classification.*** Class II (performance standards).

§ 870.1310 Vessel dilator for percutaneous catheterization.

(a) ***Identification.*** A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.

(b) ***Classification.*** Class II (performance standards).

§ 870.1330 Catheter guide wire.

(a) ***Identification.*** A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

(b) ***Classification.*** Class II (special controls). The device, when it is a torque device that is manually operated, non-patient contacting, and intended to manipulate non-cerebral vascular guide wires, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71811, Dec. 30, 2019]

§ 870.1340 Catheter introducer.

(a) ***Identification.*** A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.

(b) ***Classification.*** Class II (performance standards).

§ 870.1342 Reverse central venous recanalization system.

(a) ***Identification.*** A reverse central venous recanalization system is a prescription device for obtaining central venous access to facilitate catheter insertion into the central venous system. Reverse recanalization involves the initiation of an access path from within the vein and then progressing to the skin for patients with upper body venous occlusions or other conditions that preclude central venous access by other methods.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must fulfill the following:

(i) Demonstrate the ability to safely deliver, deploy, and remove the device; and

(ii) Evaluate all adverse events including death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, and hematoma.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Simulated-use testing in a clinically relevant bench anatomic model to assess the delivery, deployment, and retrieval of the system;

(ii) Compatibility with other devices labeled for use with the device;

(iii) Tensile strengths of joints and components;

(iv) Kink resistance of system components;

(v) Radiopacity of components used to monitor procedure under fluoroscopy;

(vi) Characterization and verification of all dimensions; and

(vii) Leakage of air or fluid.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Labeling for the device must include:

(i) Instructions for use, including a description of compatible devices;

(ii) A detailed summary of the clinical testing conducted and;

(iii) Shelf life and storage conditions.

[87 FR 26991, May 6, 2022]

§ 870.1345 Intravascular bleed monitor.

(a) ***Identification.*** An intravascular bleed monitor is a probe, catheter, or catheter introducer that measures changes in bioimpedance and uses an algorithm to detect or monitor progression of potential internal bleeding complications.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) In vivo animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use and evaluate the following:

(i) Device performance characteristics;

(ii) Adverse effects, including gross necropsy and histopathology; and

(iii) Device usability, including device preparation, device handling, and user interface.

(2) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Tensile testing of joints and materials;

(ii) Mechanical integrity testing;

(iii) Friction testing;

(iv) Flush testing;

(v) Air leakage and liquid leakage testing;

(vi) Latching and unlatching testing;

(vii) Kink and bend testing;

(viii) Insertion force testing;

(ix) Torque testing;

(x) Corrosion testing; and

(xi) Dimensional tolerance testing.

(3) Performance data must support the sterility and pyrogenicity of the device components intended to be provided sterile.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(5) The patient contacting components of the device must be demonstrated to be biocompatible.

(6) Software verification, validation, and hazard analysis must be performed.

(7) Performance data must demonstrate electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety.

(8) Human factors performance evaluation must demonstrate that the user can correctly use the device, based solely on reading the directions for use.

(9) Labeling must include:

(i) Instructions for use;

(ii) A shelf life and storage conditions;

(iii) Compatible procedures;

(iv) A sizing table; and

(v) Quantification of blood detected.

[87 FR 34778, June 8, 2022]

§ 870.1350 Catheter balloon repair kit.

(a) ***Identification.*** A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of a PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any catheter balloon repair kit that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a catheter balloon repair kit that was in commercial distribution before May 28, 1976. Any other catheter balloon repair kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.1360 Trace microsphere.

(a) ***Identification.*** A trace microsphere is a radioactively tagged nonbiodegradable particle that is intended to be injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of a PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any trace microsphere that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a trace microsphere that was in commercial distribution before May 28, 1976. Any other trace microsphere shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.1370 Catheter tip occluder.

(a) ***Identification.*** A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

(b) ***Classification.*** Class II (performance standards).

§ 870.1380 Catheter stylet.

(a) ***Identification.*** A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.

(b) ***Classification.*** Class II (performance standards).

§ 870.1390 Trocar.

(a) ***Identification.*** A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

(b) ***Classification.*** Class II (special controls). Except for trocars that are reprocessed for multiple use, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71811, Dec. 30, 2019]

§ 870.1405 Interventional cardiovascular implant simulation software device.

(a) ***Identification.*** An interventional cardiovascular implant simulation software device is a prescription device that provides a computer simulation of an interventional cardiovascular implant device inside a patient's cardiovascular anatomy. It performs computational modeling to predict the interaction of the interventional cardiovascular implant device with the patient-specific anatomical environment.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Software verification, validation, and hazard analysis, with identification of appropriate mitigations, must be performed, including a full verification and validation of the software according to the predefined software specifications.

(2) Computational modeling verification and validation activities must be performed to establish the predictive capability of the device for its indications for use.

(3) Performance validation testing must be provided to demonstrate the accuracy and clinical relevance of the modeling methods for the intended implantation simulations, including the following:

(i) Computational modeling results must be compared to clinical data supporting the indications for use to demonstrate accuracy and clinical meaningfulness of the simulations;

(ii) Agreement between computational modeling results and clinical data must be assessed and demonstrated across the full intended operating range (*e.g.,* full range of patient population, implant device sizes and patient anatomic morphologies). Any selection criteria or limitations of the samples must be described and justified;

(iii) Endpoints (*e.g.,* performance goals) and sample sizes established must be justified as to how they were determined and why they are clinically meaningful; and

(iv) Validation must be performed and controls implemented to characterize and ensure consistency (*i.e.,* repeatability and reproducibility) of modeling outputs:

(A) Testing must be performed using multiple qualified operators and using the procedure that will be implemented under anticipated conditions of use; and

(B) The factors (*e.g.,* medical imaging dataset, operator) must be identified regarding which were held constant and which were varied during the evaluation, and a description must be provided for the computations and statistical analyses used to evaluate the data.

(4) Human factors evaluation must be performed to evaluate the ability of the user interface and labeling to allow for intended users to correctly use the device and interpret the provided information.

(5) Device labeling must be provided that describes the following:

(i) Warnings that identify anatomy and image acquisition factors that may impact simulation results and provide cautionary guidance for interpretation of the provided simulation results;

(ii) Device simulation inputs and outputs, and key assumptions made in the simulation and determination of simulated outputs; and

(iii) The computational modeling performance of the device for presented simulation outputs, and the supporting evidence for this performance.

[87 FR 79803, Dec. 28, 2022]

§ 870.1415 Coronary vascular physiologic simulation software device.

(a) ***Identification.*** A coronary vascular physiologic simulation software device is a prescription device that provides simulated functional assessment of blood flow in the coronary vascular system using data extracted from medical device imaging to solve algorithms and yield simulated metrics of physiologic information (*e.g.,* blood flow, coronary flow reserve, fractional flow reserve, myocardial perfusion). A coronary vascular physiologic simulation software device is intended to generate results for use and review by a qualified clinician.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Adequate software verification and validation based on comprehensive hazard analysis, with identification of appropriate mitigations, must be performed, including:

(i) Full characterization of the technical parameters of the software, including:

(A) Any proprietary algorithm(s) used to model the vascular anatomy; and

(B) Adequate description of the expected impact of all applicable image acquisition hardware features and characteristics on performance and any associated minimum specifications;

(ii) Adequate consideration of privacy and security issues in the system design; and

(iii) Adequate mitigation of the impact of failure of any subsystem components (*e.g.,* signal detection and analysis, data storage, system communications and cybersecurity) with respect to incorrect patient reports and operator failures.

(2) Adequate non-clinical performance testing must be provided to demonstrate the validity of computational modeling methods for flow measurement; and

(3) Clinical data supporting the proposed intended use must be provided, including the following:

(i) Output measure(s) must be compared to a clinically acceptable method and must adequately represent the simulated measure(s) the device provides in an accurate and reproducible manner;

(ii) Clinical utility of the device measurement accuracy must be demonstrated by comparison to that of other available diagnostic tests (*e.g.,* from literature analysis);

(iii) Statistical performance of the device within clinical risk strata (*e.g.,* age, relevant comorbidities, disease stability) must be reported;

(iv) The dataset must be adequately representative of the intended use population for the device (*e.g.,* patients, range of vessel sizes, imaging device models). Any selection criteria or limitations of the samples must be fully described and justified;

(v) Statistical methods must consider the predefined endpoints:

(A) Estimates of probabilities of incorrect results must be provided for each endpoint,

(B) Where multiple samples from the same patient are used, statistical analysis must not assume statistical independence without adequate justification, and

(C) The report must provide appropriate confidence intervals for each performance metric;

(vi) Sensitivity and specificity must be characterized across the range of available measurements;

(vii) Agreement of the simulated measure(s) with clinically acceptable measure(s) must be assessed across the full range of measurements;

(viii) Comparison of the measurement performance must be provided across the range of intended image acquisition hardware; and

(ix) If the device uses a cutoff threshold or operates across a spectrum of disease, it must be established prior to validation, and it must be justified as to how it was determined and clinically validated;

(4) Adequate validation must be performed and controls implemented to characterize and ensure consistency (*i.e.,* repeatability and reproducibility) of measurement outputs:

(i) Acceptable incoming image quality control measures and the resulting image rejection rate for the clinical data must be specified, and

(ii) Data must be provided within the clinical validation study or using equivalent datasets demonstrating the consistency (*i.e.,* repeatability and reproducibility) of the output that is representative of the range of data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment;

(A) Testing must be performed using multiple operators meeting planned qualification criteria and using the procedure that will be implemented in the production use of the device, and

(B) The factors (*e.g.,* medical imaging dataset, operator) must be identified regarding which were held constant and which were varied during the evaluation, and a description must be provided for the computations and statistical analyses used to evaluate the data;

(5) Human factors evaluation and validation must be provided to demonstrate adequate performance of the user interface to allow for users to accurately measure intended parameters, particularly where parameter settings that have impact on measurements require significant user intervention; and

(6) Device labeling must be provided that adequately describes the following:

(i) The device's intended use, including the type of imaging data used, what the device measures and outputs to the user, whether the measure is qualitative or quantitative, the clinical indications for which it is to be used, and the specific population for which the device use is intended;

(ii) Appropriate warnings specifying the intended patient population, identifying anatomy and image acquisition factors that may impact measurement results, and providing cautionary guidance for interpretation of the provided measurements;

(iii) Key assumptions made in the calculation and determination of simulated measurements;

(iv) The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance. Per-vessel clinical performance, including where applicable localized performance according to vessel and segment, must be included as well as a characterization of the measurement error across the expected range of measurement for key parameters based on the clinical data;

(v) A detailed description of the patients studied in the clinical validation (*e.g.,* age, gender, race or ethnicity, clinical stability, current treatment regimen) as well as procedural details of the clinical study (*e.g.,* scanner representation, calcium scores, use of beta-blockers or nitrates); and

(vi) Where significant human interface is necessary for accurate analysis, adequately detailed description of the analysis procedure using the device and any data features that could affect accuracy of results.

[80 FR 63673, Oct. 21, 2015]

§ 870.1420 Coronary artery disease risk indicator using acoustic heart signals.

(a) ***Identification.*** A coronary artery disease risk indicator using acoustic heart signals is a device that records heart sounds including murmurs and vibrations to calculate a patient-specific risk of presence of coronary artery disease, as an aid in cardiac analysis and diagnosis.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must fulfill the following:

(i) Testing must include a discussion of the patient population and any statistical techniques used for analyzing the data; and

(ii) Testing must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(2) Acoustic performance testing must evaluate microphone sensitivity, sound acquisition bandwidth, and amplitude accuracy. The acoustic sensor specifications and mechanism used to capture heart sounds must be described.

(3) A scientific justification for the validity of the algorithm(s) must be provided. This justification must fulfill the following:

(i) All inputs and outputs of the algorithm must be fully described;

(ii) The procedure for segmenting, characterizing, and classifying the acoustic signal must be fully described; and

(iii) This justification must include verification of the algorithm calculations and validation using an independent data set.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Human factors/usability testing must demonstrate that the user can correctly use the device, including device placement, based solely on reading the directions for use.

(7) Performance data must demonstrate the electromagnetic compatibility and electrical safety of the device.

(8) Labeling must include the following:

(i) A description of what the device measures and outputs to the user;

(ii) Instructions for proper placement of the device;

(iii) Instructions on care and cleaning of the device;

(iv) Warnings identifying sensor acquisition factors that may impact measurement results and instructions for mitigating these factors; and

(v) The expected performance of the device for all intended use populations and environments.

[87 FR 32990, June 1, 2022]

§ 870.1425 Programmable diagnostic computer.

(a) ***Identification.*** A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

(b) ***Classification.*** Class II (performance standards).

§ 870.1435 Single-function, preprogrammed diagnostic computer.

(a) ***Identification.*** A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

(b) ***Classification.*** Class II (performance standards).

§ 870.1450 Densitometer.

(a) ***Identification.*** A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

(b) ***Classification.*** Class II (performance standards).

§ 870.1650 Angiographic injector and syringe.

(a) ***Identification.*** An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

(b) ***Classification.*** Class II (special controls). The device, when it is a non-patient contacting balloon inflation syringe intended only to inflate/deflate balloon catheters and monitor pressure within the balloon, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71811, Dec. 30, 2019]

§ 870.1660 Indicator injector.

(a) ***Identification.*** An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjuction with a densitometer or thermodilution device to determine cardiac output.

(b) ***Classification.*** Class II (performance standards).

§ 870.1670 Syringe actuator for an injector.

(a) ***Identification.*** A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

(b) ***Classification.*** Class II (performance standards).

§ 870.1750 External programmable pacemaker pulse generator.

(a) ***Identification.*** An external programmable pacemaker pulse generators is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

(b) ***Classification.*** Class II (performance standards).

§ 870.1800 Withdrawal-infusion pump.

(a) ***Identification.*** A withdrawal-infusion pump is a device designed to inject accurately drugs into the bloodstream and to withdraw blood samples for use in determining cardiac output.

(b) ***Classification.*** Class II (performance standards).

§ 870.1875 Stethoscope.

(a) ***Manual stethoscope*** —

(1) ***Identification.*** A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

(b) ***Electronic stethoscope*** —

(1) ***Identification.*** An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) ***Classification.*** Class II (special controls). The device, when it is a lung sound monitor, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38796, July 25, 2001; 84 FR 71811, Dec. 30, 2019]

§ 870.1915 Thermodilution probe.

(a) ***Identification.*** A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

(b) ***Classification.*** Class II (performance standards).

Subpart C—Cardiovascular Monitoring Devices

§ 870.2050 Biopotential amplifier and signal conditioner.

(a) ***Identification.*** A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

(b) ***Classification.*** Class II (performance standards).

§ 870.2060 Transducer signal amplifier and conditioner.

(a) ***Identification.*** A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.

(b) ***Classification.*** Class II (performance standards).

§ 870.2100 Cardiovascular blood flowmeter.

(a) ***Identification.*** A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

(b) ***Classification.*** Class II (performance standards).

§ 870.2120 Extravascular blood flow probe.

(a) ***Identification.*** An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

(b) ***Classification.*** Class II (performance standards).

§ 870.2200 Adjunctive cardiovascular status indicator.

(a) ***Identification.*** The adjunctive cardiovascular status indicator is a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Software description, verification, and validation based on comprehensive hazard analysis must be provided, including:

(i) Full characterization of technical parameters of the software, including any proprietary algorithm(s);

(ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;

(iii) Specification of acceptable incoming sensor data quality control measures; and

(iv) Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on accuracy of patient reports.

(2) Scientific justification for the validity of the status indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modeling.

(3) Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.

(4) Clinical data must be provided in support of the intended use and include the following:

(i) Output measure(s) must be compared to an acceptable reference method to demonstrate that the output measure(s) represent(s) the predictive measure(s) that the device provides in an accurate and reproducible manner;

(ii) The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified;

(iii) Agreement of the measure(s) with the reference measure(s) must be assessed across the full measurement range; and

(iv) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment.

(5) Labeling must include the following:

(i) The type of sensor data used, including specification of compatible sensors for data acquisition;

(ii) A description of what the device measures and outputs to the user;

(iii) Warnings identifying sensor reading acquisition factors that may impact measurement results;

(iv) Guidance for interpretation of the measurements, including warning(s) specifying adjunctive use of the measurements;

(v) Key assumptions made in the calculation and determination of measurements;

(vi) The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance; and

(vii) A detailed description of the patients studied in the clinical validation (*e.g.,* age, gender, race/ethnicity, clinical stability) as well as procedural details of the clinical study.

[82 FR 35067, July 28, 2017]

§ 870.2210 Adjunctive predictive cardiovascular indicator.

(a) ***Identification.*** The adjunctive predictive cardiovascular indicator is a prescription device that uses software algorithms to analyze cardiovascular vital signs and predict future cardiovascular status or events. This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must be provided, including:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications;

(iii) A description of sensor data quality control measures;

(iv) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy;

(v) A description of the expected time to patient status or clinical event for all expected outputs, accounting for differences in patient condition and environment; and

(vi) The sensitivity, specificity, positive predictive value, and negative predictive value in both percentage and number form.

(2) A scientific justification for the validity of the predictive cardiovascular indicator algorithm(s) must be provided. This justification must include verification of the algorithm calculations and validation using an independent data set.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of misinterpretation of device output.

(4) A clinical data assessment must be provided. This assessment must fulfill the following:

(i) The assessment must include a summary of the clinical data used, including source, patient demographics, and any techniques used for annotating and separating the data.

(ii) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(iii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iv) The assessment must evaluate how the device output correlates with the predicted event or status.

(5) Labeling must include:

(i) A description of what the device measures and outputs to the user;

(ii) Warnings identifying sensor acquisition factors that may impact measurement results;

(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;

(iv) A specific time or a range of times before the predicted patient status or clinical event occurs, accounting for differences in patient condition and environment;

(v) Key assumptions made during calculation of the output;

(vi) The type(s) of sensor data used, including specification of compatible sensors for data acquisition;

(vii) The expected performance of the device for all intended use populations and environments; and

(viii) Relevant characteristics of the patients studied in the clinical validation (including age, gender, race or ethnicity, and patient condition) and a summary of validation results.

[87 FR 8191, Feb. 14, 2022]

§ 870.2220 Adjunctive hemodynamic indicator with decision point.

(a) ***Identification.*** An adjunctive hemodynamic indicator with decision point is a device that identifies and monitors hemodynamic condition(s) of interest and provides notifications at a clinically meaningful decision point. This device is intended to be used adjunctively along with other monitoring and patient information.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Software description, verification, and validation based on comprehensive hazard analysis and risk assessment must be provided, including:

(i) Full characterization of technical parameters of the software, including algorithm(s);

(ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;

(iii) Specification of acceptable incoming sensor data quality control measures;

(iv) Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on output accuracy; and

(v) The sensitivity, specificity, positive predictive value, and negative predictive value in both percentage and number form for clinically meaningful pre-specified time windows consistent with the device output.

(2) Scientific justification for the validity of the hemodynamic indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm must use an independent data set.

(3) Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.

(4) Clinical data must support the intended use and include the following:

(i) The assessment must include a summary of the clinical data used, including source, patient demographics, and any techniques used for annotating and separating the data;

(ii) Output measure(s) must be compared to an acceptable reference method to demonstrate that the output represents the measure(s) that the device provides in an accurate and reproducible manner;

(iii) The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified;

(iv) Where continuous measurement variables are displayed, agreement of the output with the reference measure(s) must be assessed across the full measurement range; and

(v) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment.

(5) Labeling must include the following:

(i) The type of sensor data used, including specification of compatible sensors for data acquisition, and a clear description of what the device measures and outputs to the user;

(ii) Warnings identifying factors that may impact output results;

(iii) Guidance for interpretation of the outputs, including warning(s) specifying adjunctive use of the measurements;

(iv) Key assumptions made in the calculation and determination of measurements; and

(v) A summary of the clinical validation data, including details of the patient population studied (*e.g.,* age, gender, race/ethnicity), clinical study protocols, and device performance with confidence intervals for all intended use populations.

[87 FR 79254, Dec. 27, 2022]

§ 870.2300 Cardiac monitor (including cardiotachometer and rate alarm).

(a) ***Identification.*** A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(b) ***Classification.*** Class II (performance standards).

§ 870.2310 Apex cardiograph (vibrocardiograph).

(a) ***Identification.*** An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.

(b) ***Classification.*** Class II (performance standards).

§ 870.2320 Ballistocardiograph.

(a) ***Identification.*** A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.

(b) ***Classification.*** Class II (performance standards).

§ 870.2330 Echocardiograph.

(a) ***Identification.*** An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

(b) ***Classification.*** Class II (performance standards).

§ 870.2340 Electrocardiograph.

(a) ***Identification.*** An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.

(b) ***Classification.*** Class II (performance standards).

§ 870.2345 Electrocardiograph software for over-the-counter use.

(a) ***Identification.*** An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing under anticipated conditions of use must demonstrate the following:

(i) The ability to obtain an electrocardiograph of sufficient quality for display and analysis; and

(ii) The performance characteristics of the detection algorithm as reported by sensitivity and either specificity or positive predictive value.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(3) Non-clinical performance testing must validate detection algorithm performance using a previously adjudicated data set.

(4) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the device labeling; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

(5) Labeling must include:

(i) Hardware platform and operating system requirements;

(ii) Situations in which the device may not operate at an expected performance level;

(iii) A summary of the clinical performance testing conducted with the device;

(iv) A description of what the device measures and outputs to the user; and

(v) Guidance on interpretation of any results.

[86 FR 2549, Jan. 18, 2022]

§ 870.2350 Electrocardiograph lead switching adaptor.

(a) ***Identification.*** An electrocardiograph lead switching adaptor is a passive switching device to which electrocardiograph limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

(b) ***Classification.*** Class II (performance standards).

§ 870.2360 Electrocardiograph electrode.

(a) ***Identification.*** An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9. The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Electrocardiograph Electrodes." See § 870.1(e) for availability information of guidance documents.

[45 FR 7907, Feb. 5, 1980, as amended at 76 FR 43585, July 21, 2011]

§ 870.2370 Electrocardiograph surface electrode tester.

(a) ***Identification.*** An electrocardiograph surface electrode tester is a device used to test the function and application of electrocardiograph electrodes.

(b) ***Classification.*** Class II (performance standards).

§ 870.2390 Phonocardiograph.

(a) ***Identification.*** A phonocardiograph is a device used to amplify or condition the signal from a heart sound transducer. This device furnishes the excitation energy for the transducer and provides a visual or audible display of the heart sounds.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2400 Vectorcardiograph.

(a) ***Identification.*** A vectorcardiograph is a device used to process the electrical signal transmitted through electrocardiograph electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

(b) ***Classification.*** Class II (performance standards).

§ 870.2450 Medical cathode-ray tube display.

(a) ***Identification.*** A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.

(b) ***Classification.*** Class II (performance standards).

§ 870.2600 Signal isolation system.

(a) ***Identification.*** A signal isolation system is a device that electrically isolates the patient from equipment connected to the commercial power supply received from a utility company. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2620 Line isolation monitor.

(a) ***Identification.*** A line isolation monitor is a device used to monitor the electrical leakage current from a power supply electrically isolated from the commercial power supply received from a utility company.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2640 Portable leakage current alarm.

(a) ***Identification.*** A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2675 Oscillometer.

(a) ***Identification.*** An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.2700 Oximeter.

(a) ***Identification.*** An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

(b) ***Classification.*** Class II (performance standards).

§ 870.2710 Ear oximeter.

(a) ***Identification.*** An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

(b) ***Classification.*** Class II (performance standards).

§ 870.2750 Impedance phlebograph.

(a) ***Identification.*** An impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.

(b) ***Classification.*** Class II (performance standards).

§ 870.2770 Impedance plethysmograph.

(a) ***Identification.*** An impedance plethysmograph is a device used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs.

(b) ***Classification.*** Class II (special controls). The device, when it is a body composition analyzer which is not intended to diagnose or treat any medical condition, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.

(a) ***Identification.*** A hydraulic, pneumatic, or photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.

(b) ***Classification.*** Class II (performance standards).

§ 870.2785 Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

(a) ***Identification.*** The device uses software algorithms to analyze video signal and estimate pulse rate, heart rate, breathing rate, and/or respiratory rate. This device is not intended to independently direct therapy.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) If required image acquisition hardware is not included with the device, full specifications of the hardware requirements and testing to demonstrate the specified hardware ensures adequate data for validated and accurate measurements;

(iii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications;

(iv) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy; and

(v) Software documentation must include a cybersecurity vulnerability and management process to assure software functionality.

(2) Clinical data must be provided. This assessment must fulfill the following:

(i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iii) The assessment must compare device output with a clinically accurate patient-contacting relevant comparator device in an accurate and reproducible manner.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.

(4) Labeling must include:

(i) A description of what the device measures and outputs to the user;

(ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (garment types/textures, motion, etc.) that may impact measurement results;

(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;

(iv) The expected performance of the device for all intended use populations and environments; and

(v) Robust instructions to ensure correct system setup.

[88 CFR 6167, Jan. 31, 2023]

§ 870.2786 Hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

(a) ***Identification.*** The device uses an optical sensor system and software algorithms to obtain and analyze video signal and estimate pulse rate, heart rate, breathing rate, and/or respiratory rates. This device is not intended to independently direct therapy.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy; and

(iii) Software documentation must include a cybersecurity vulnerability and management process to assure software functionality.

(2) Performance testing must demonstrate the safety of any illuminating optics.

(3) Clinical data must be provided. This assessment must fulfill the following:

(i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iii) The assessment must compare device output with a clinically accurate patient-contacting relevant comparator device in an accurate and reproducible manner.

(4) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.

(5) Labeling must include:

(i) A description of what the device measures and outputs to the user;

(ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (garment types/textures, motion, etc.) that may impact measurement results;

(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;

(iv) The expected performance of the device for all intended use populations and environments; and

(v) Robust instructions to ensure correct system setup.

[88 FR 976, Jan. 6, 2023]

§ 870.2790 Photoplethysmograph analysis software for over-the-counter use.

(a) ***Identification.*** A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate the performance characteristics of the detection algorithm under anticipated conditions of use.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmograph signal quality.

(4) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the device labeling; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

(5) Labeling must include:

(i) Hardware platform and operating system requirements;

(ii) Situations in which the device may not operate at an expected performance level;

(iii) A summary of the clinical performance testing conducted with the device;

(iv) A description of what the device measures and outputs to the user; and

(v) Guidance on interpretation of any results.

[87 FR 6419, Feb. 4, 2022]

§ 870.2800 Medical magnetic tape recorder.

(a) ***Identification.*** A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

(b) ***Classification.*** Class II (performance standards).

§ 870.2810 Paper chart recorder.

(a) ***Identification.*** A paper chart recorder is a device used to print on paper, and create a permanent record of the signal from, for example, a physiological amplifier, signal conditioner, or computer.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.2840 Apex cardiographic transducer.

(a) ***Identification.*** An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.

(b) ***Classification.*** Class II (performance standards).

§ 870.2850 Extravascular blood pressure transducer.

(a) ***Identification.*** An extravascular blood pressure transducer is a device used to measure blood pressure by changes in the mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to the electrical or mechanical changes produced in the transducer.

(b) ***Classification.*** Class II (performance standards).

§ 870.2855 Implantable Intra-aneurysm Pressure Measurement System.

(a) ***Identification.*** Implantable intra-aneurysm pressure measurement system is a device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

(b) ***Classification.*** Class II (special controls). The special control is FDA's guidance document entitled “Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System.” See § 870.1 (e) for the availability of this guidance document.

[71 FR 7871, Feb. 15, 2006]

§ 870.2860 Heart sound transducer.

(a) ***Identification.*** A heart sound transducer is an external transducer that exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

(b) ***Classification.*** Class II (performance standards).

§ 870.2870 Catheter tip pressure transducer.

(a) ***Identification.*** A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

(b) ***Classification.*** Class II (performance standards).

§ 870.2880 Ultrasonic transducer.

(a) ***Identification.*** An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

(b) ***Classification.*** Class II (performance standards).

§ 870.2890 Vessel occlusion transducer.

(a) ***Identification.*** A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) ***Classification.*** Class II (performance standards).

§ 870.2900 Patient transducer and electrode cable (including connector).

(a) ***Identification.*** A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

(b) ***Classification.*** Class II (performance standards).

§ 870.2910 Radiofrequency physiological signal transmitter and receiver.

(a) ***Identification.*** A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

(b) ***Classification.*** Class II (performance standards).

§ 870.2920 Telephone electrocardiograph transmitter and receiver.

(a) ***Identification.*** A telephone electrocardiograph transmitter and receiver is a device used to condition an electrocardiograph signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.

(b) ***Classification.*** Class II (performance standards).

Subpart D—Cardiovascular Prosthetic Devices

§ 870.3250 Vascular clip.

(a) ***Identification.*** A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels other than intracranial vessels.

(b) ***Classification.*** Class II (performance standards).

§ 870.3260 Vena cava clip.

(a) ***Identification.*** A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

(b) ***Classification.*** Class II (performance standards).

§ 870.3300 Vascular embolization device.

(a) ***Identification.*** A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see § 882.5950 of this chapter.

(b) ***Classification.*** Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." For availability of this guidance document, see § 870.1(e).

[69 FR 77899, Dec. 29, 2004]

§ 870.3375 Cardiovascular intravascular filter.

(a) ***Identification.*** A cardiovascular intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.

(b) ***Classification.*** Class II. The special controls for this device are:

(1) "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,' " and

(2) FDA's:

(i) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)" and

(ii) "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions."

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 870.3450 Vascular graft prosthesis.

(a) ***Identification.*** A vascular graft prosthesis is an implanted device intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access. It is commonly constructed of materials such as polyethylene terephthalate and polytetrafluoroethylene, and it may be coated with a biological coating, such as albumin or collagen, or a synthetic coating, such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords.

(b) ***Classification.*** Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance Document for Vascular Prostheses 510(k) Submissions."

[66 FR 18542, Apr. 10, 2001]

§ 870.3460 Endovascular Suturing System.

(a) ***Identification.*** An endovascular suturing system is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery. The system is comprised of the implant device and an endovascular delivery device used to implant the endovascular suture.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) The device should be demonstrated to be biocompatible;

(2) Sterility and shelf life testing should demonstrate the sterility of patient-contacting components and the shelf-life of these components;

(3) Non-clinical and clinical performance testing should demonstrate substantial equivalence in safety and effectiveness, including durability, compatibility, migration resistance, corrosion resistance, and delivery and deployment;

(4) Non-clinical testing should evaluate the compatibility of the device in an magnetic resonance (MR) environment;

(5) Appropriate analysis and non-clinical testing should validate electromagnetic compatibility (EMC) and electrical safety;

(6) The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109 of this chapter; and

(7) Labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including a detailed summary of the non-clinical and clinical evaluations pertinent to use of the device.

[77 FR 8119, Feb. 14, 2012]

§ 870.3470 Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.

(a) ***Identification.*** An intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

(b) ***Classification.*** Class II (performance standards).

§ 870.3535 Intra-aortic balloon and control system.

(a) ***Identification.*** An intra-aortic balloon and control system is a prescription device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

(b) ***Classification.***

(1) Class II (special controls) when the device is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure. The special controls for this device are:

(i) Appropriate analysis and non-clinical testing must be conducted to validate electromagnetic compatibility and electrical safety of the device;

(ii) Software verification, validation, and hazard analysis must be performed;

(iii) The device must be demonstrated to be biocompatible;

(iv) Sterility and shelf-life testing must demonstrate the sterility of patient-contacting components and the shelf life of these components;

(v) Non-clinical performance evaluation of the device must demonstrate mechanical integrity, durability, and reliability to support its intended purpose; and

(vi) Labeling must include a detailed summary of the device- and procedure-related complications pertinent to use of the device.

(2) Class III (premarket approval) when the device is indicated for septic shock and pulsatile flow generation.

(c) ***Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 31, 2014, for any intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation that was in commercial distribution before May 28, 1976, or that has, on or before March 31, 2014, been found to be substantially equivalent to any intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation that was in commercial distribution before May 28, 1976. Any other intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[78 FR 79303, Dec. 31, 2013]

§ 870.3545 Ventricular bypass (assist) device.

(a) ***Identification.*** A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976. Any other ventricular bypass (assist) device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 76 FR 50666, Aug. 16, 2011]

§ 870.3600 External pacemaker pulse generator.

(a) ***Identification.*** An external pacemaker pulse generator (EPPG) is a prescription device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (*i.e.,* battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (*e.g.* data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the EPPG device. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (*e.g.,* overdrive pacing or automatic mode switching); and

(v) Appropriate electromagnetic compatibility information must be included.

[81 FR 22529, Apr. 18, 2016]

§ 870.3605 Pacing system analyzer.

(a) ***Identification.*** A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3600). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (*i.e.,* battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (*e.g.* data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the PSA. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (*e.g.*, overdrive pacing or automatic mode switching);

(v) Labeling must limit the use of external pacing to the implant procedure; and

(vi) Appropriate electromagnetic compatibility information must be included.

[81 FR 22350, Apr. 18, 2016]

§ 870.3610 Implantable pacemaker pulse generator.

(a) ***Identification.*** An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 20, 2012, for any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976, or that has, on or before September 20, 2012, been found to be substantially equivalent to any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 77 FR 37576, June 22, 2012]

§ 870.3620 Pacemaker lead adaptor.

(a) ***Identification.*** A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

(b) ***Classification.*** Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions.”

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.3630 Pacemaker generator function analyzer.

(a) ***Identification.*** A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

(b) ***Classification.*** Class II (performance standards).

§ 870.3640 Indirect pacemaker generator function analyzer.

(a) ***Identification.*** An indirect pacemaker generator function analyzer is an electrically powered device that is used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and width via external electrodes in contact with the patient's skin.

(b) ***Classification.*** Class II (performance standards).

§ 870.3650 Pacemaker polymeric mesh bag.

(a) ***Identification.*** A pacemaker polymeric mesh bag is an implanted device used to hold a pacemaker pulse generator. The bag is designed to create a stable implant environment for the pulse generator.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.3670 Pacemaker charger.

(a) ***Identification.*** A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

(a) ***Temporary pacemaker electrode*** —

(1) ***Identification.*** A temporary pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an *external* pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) ***Classification.*** Class II (performance standards).

(b) ***Permanent pacemaker electrode*** —

(1) ***Identification.*** A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 4, 2012, for any permanent pacemaker electrode device that was in commercial distribution before May 28, 1976, or that has, on or before October 4, 2012, been found to be substantially equivalent to any permanent pacemaker electrode device that was in commercial distribution before May 28, 1976. Any other pacemaker repair or replacement material device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 77 FR 39927, July 6, 2012]

§ 870.3690 Pacemaker test magnet.

(a) ***Identification.*** A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.3700 Pacemaker programmers.

(a) ***Identification.*** A pacemaker programmer is a device used to noninvasively change one or more of the electrical operating characteristics of a pacemaker.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 20, 2012, for any pacemaker programmer that was in commercial distribution before May 28, 1976, or that has, on or before September 20, 2012, been found to be substantially equivalent to any pacemaker programmer that was in commercial distribution before May 28, 1976. Any other pacemaker programmer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 77 FR 37573, June 22, 2012]

§ 870.3710 Pacemaker repair or replacement material.

(a) ***Identification.*** A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any pacemaker repair or replacement material device that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any pacemaker repair

or replacement material device that was in commercial distribution before May 28, 1976. Any other pacemaker repair or replacement material device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 76 FR 50666, Aug. 16, 2011]

§ 870.3720 Pacemaker electrode function tester.

(a) ***Identification.*** A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential.

(b) ***Classification.*** Class II (performance standards).

§ 870.3730 Pacemaker service tools.

(a) ***Identification.*** Pacemaker service tools are devices such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker generator.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989; 66 FR 38797, July 25, 2001]

§ 870.3800 Annuloplasty ring.

(a) ***Identification.*** An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

(b) ***Classification.*** Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Annuloplasty Rings 510(k) Submissions.”

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.3850 Carotid sinus nerve stimulator.

(a) ***Identification.*** A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of a PDP is required.*** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976. Any other carotid sinus nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.3925 Replacement heart valve.

(a) ***Identification.*** A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) ***Classification.*** Class III (premarket approval).

(c) ***Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.*** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 9, 1987 for any replacement heart valve that was in commercial distribution before May 28, 1976, or that has on or before December 9, 1987 been found to be substantially equivalent to a replacement heart valve that was in commercial distribution before May 28, 1976. Any other replacement heart valve shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 18163, May 13, 1987; 52 FR 23137, June 17, 1987]

§ 870.3935 Prosthetic heart valve holder.

(a) ***Identification.*** A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

(b) ***Classification.*** Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996]

§ 870.3945 Prosthetic heart valve sizer.

(a) ***Identification.*** A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38797, July 25, 2001]

Subpart E—Cardiovascular Surgical Devices

§ 870.4075 Endomyocardial biopsy device.

(a) ***Identification.*** An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart.

(b) ***Classification.*** Class II (performance standards).

§ 870.4100 Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure.

(a) ***Identification.*** An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (*e.g.,* monitors, detectors, sensors, connectors).

(b) ***Classification*** —Class II (special controls). The special controls for this device are:

(1) The technological characteristics of the device must ensure that the geometry and design parameters are consistent with the intended use, and that the devices and accessories in the circuit are compatible;

(2) The devices and accessories in the circuit must be demonstrated to be biocompatible;

(3) Sterility and shelf-life testing must demonstrate the sterility of any patient-contacting devices and accessories in the circuit and the shelf life of these devices and accessories;

(4) Non-clinical performance evaluation of the devices and accessories in the circuit must demonstrate substantial equivalence of the performance characteristics on the bench, mechanical integrity, electromagnetic compatibility (where applicable), software, durability, and reliability;

(5) In vivo evaluation of the devices and accessories in the circuit must demonstrate their performance over the intended duration of use, including a detailed summary of the clinical evaluation pertinent to the use of the devices and accessories to demonstrate their effectiveness if a specific indication (patient population and/or condition) is identified; and

(6) Labeling must include a detailed summary of the non-clinical and in vivo evaluations pertinent to use of the devices and accessories in the circuit and adequate instructions with respect to anticoagulation, circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure.

[81 FR 7451, Feb. 12, 2016]

§ 870.4150 Extracorporeal system for carbon dioxide removal.

(a) ***Identification.*** An extracorporeal system for carbon dioxide removal is a system of devices and accessories that provides assisted extracorporeal carbon dioxide removal from the patient's blood in patients with acute respiratory failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, a gas exchanger, blood pump, cannulae, tubing, filters, and other accessories (*e.g.,* monitors, detectors, sensors, connectors).

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) In vivo evaluation, which may include animal testing and clinical data, of the devices and accessories in the circuit must demonstrate their performance over the intended duration of use, including a detailed summary of the in vivo evaluation pertinent to the use of the devices and accessories to demonstrate their effectiveness.

(2) The technological characteristics of the device must ensure that the geometry and design parameters are consistent with the intended use, and that the devices and accessories in the circuit are compatible.

(3) Non-clinical performance testing of the devices and accessories in the circuit must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical integrity;

(ii) Durability; and

(iii) Reliability.

(4) All patient contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must demonstrate the electrical safety and electromagnetic compatibility (EMC) of any electrical components.

(6) Software validation, verification, and hazard analysis must be performed.

(7) Performance testing must demonstrate the sterility of all patient-contacting components.

(8) Performance testing must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.

(9) Labeling must include the following:

(i) A detailed summary of the non-clinical and in vivo evaluations pertinent to use of the device and accessories in the circuit;

(ii) Adequate instructions with respect to circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure; and

(iii) A shelf life.

[87 FR 80039, Dec. 29, 2022]

§ 870.4200 Cardiopulmonary bypass accessory equipment.

(a) ***Identification.*** Cardiopulmonary bypass accessory equipment is a device that has no contact with blood and that is used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) ***Classification.***

(1) Class I. The device is classified as class I if it does not involve an electrical connection to the patient. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

(2) Class II (special controls). The device is classified as class II if it involves an electrical connection to the patient. The special controls are as follows:

(i) The performance standard under part 898 of this chapter, and

(ii) The guidance document entitled "Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables." The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

[65 FR 19319, Apr. 11, 2000]

§ 870.4205 Cardiopulmonary bypass bubble detector.

(a) ***Identification.*** A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

(b) ***Classification.*** Class II (performance standards).

§ 870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.

(a) ***Identification.*** A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.

(b) ***Classification.*** Class II (performance standards).

§ 870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) ***Identification.*** A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

(b) ***Classification.*** Class II (performance standards).

§ 870.4230 Cardiopulmonary bypass defoamer.

(a) ***Identification.*** A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.

(b) ***Classification.*** Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions."

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.4240 Cardiopulmonary bypass heat exchanger.

(a) ***Identification.*** A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.

(b) ***Classification.*** Class II (performance standards).

§ 870.4250 Cardiopulmonary bypass temperature controller.

(a) ***Identification.*** A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

(b) ***Classification.*** Class II (performance standards).

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

(a) ***Identification.*** A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

(b) ***Classification.*** Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions."

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.4270 Cardiopulmonary bypass cardiotomy suction line blood filter.

(a) ***Identification.*** A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

(b) ***Classification.*** Class II (performance standards).

§ 870.4280 Cardiopulmonary prebypass filter.

(a) ***Identification.*** A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not used to filter blood.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.

(a) ***Identification.*** A cardiopulmonary bypass adaptor, stopcock, manifold, or fitting is a device used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.4300 Cardiopulmonary bypass gas control unit.

(a) ***Identification.*** A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.

(b) ***Classification.*** Class II (performance standards).

§ 870.4310 Cardiopulmonary bypass coronary pressure gauge.

(a) ***Identification.*** A cardiopulmonary bypass coronary pressure gauge is a device used in cardiopulmonary bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

(b) ***Classification.*** Class II (performance standards).

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

(a) ***Identification.*** A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

(b) ***Classification.*** Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976. Any other cardiopulmonary bypass pulsatile flow generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 69 FR 34920, June 23, 2004]

§ 870.4330 Cardiopulmonary bypass on-line blood gas monitor.

(a) ***Identification.*** A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

(b) ***Classification.*** Class II (performance standards).

§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

(a) ***Identification.*** A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.4350 Cardiopulmonary bypass oxygenator.

(a) ***Identification.*** A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

(b) ***Classification.*** Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions."

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.4360 Nonroller-type blood pump.

(a) ***Nonroller-type cardiopulmonary and circulatory bypass blood pump*** —

(1) ***Identification.*** A nonroller-type cardiopulmonary and circulatory bypass blood pump is a prescription device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (*i.e.,* circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

(2) ***Classification*** —Class II (special controls). The special controls for this device are:

(i) Non-clinical performance testing must perform as intended over the intended duration of use and demonstrate the following: Operating parameters, dynamic blood damage, heat generation, air entrapment, mechanical integrity, and durability/reliability;

(ii) The patient-contacting components of the device must be demonstrated to be biocompatible;

(iii) Sterility and shelf life testing must demonstrate the sterility of patient-contacting components and the shelf life of these components; and

(iv) Labeling must include information regarding the duration of use, and a detailed summary of the device- and procedure-related complications pertinent to use of the device.

(b) ***Nonroller-type temporary ventricular support blood pump*** —

(1) ***Identification.*** A nonroller-type temporary ventricular support blood pump is a prescription device that uses any method resulting in blood propulsion to provide the temporary ventricular assistance required for support of the systemic and/or pulmonary circulations during periods when there is ongoing or anticipated hemodynamic instability due to immediately reversible alterations in ventricular myocardial function resulting from mechanical or physiologic causes. Duration of use would be less than 6 hours.

(2) ***Classification.*** Class III (premarket approval).

(c) ***Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.*** A PMA or notice of completion of a PDP is required to be filed with FDA on or before September 8, 2015, for any nonroller-type temporary ventricular support blood pump that was in commercial distribution before May 28, 1976, or that has, on or before September 8, 2015, been found to be substantially equivalent to any nonroller-type temporary ventricular support blood pump that was in commercial distribution before May 28, 1976. Any other nonroller-type temporary ventricular support blood pump shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[80 FR 32311, June 8, 2015]

§ 870.4370 Roller-type cardiopulmonary bypass blood pump.

(a) ***Identification.*** A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) ***Classification.*** Class II (performance standards).

§ 870.4380 Cardiopulmonary bypass pump speed control.

(a) ***Identification.*** A cardiopulmonary bypass pump speed control is a device used that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

(b) ***Classification.*** Class II (performance standards).

§ 870.4390 Cardiopulmonary bypass pump tubing.

(a) ***Identification.*** A cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.

(b) ***Classification.*** Class II (performance standards).

§ 870.4400 Cardiopulmonary bypass blood reservoir.

(a) ***Identification.*** A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.

(b) ***Classification.*** Class II (special controls), except that a reservoir that contains a defoamer or filter is classified into the same class as the defoamer or filter. The device, when it is a cardiopulmonary bypass blood reservoir that does not contain defoamers or blood filters, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.4410 Cardiopulmonary bypass in-line blood gas sensor.

(a) ***Identification.*** A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

(b) ***Classification.*** Class II (performance standards).

§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

(a) ***Identification.*** A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.4430 Cardiopulmonary bypass intracardiac suction control.

(a) ***Identification.*** A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 84 FR 71812, Dec. 30, 2019]

§ 870.4450 Vascular clamp.

(a) ***Identification.*** A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

(b) ***Classification.*** Class II (performance standards).

§ 870.4475 Surgical vessel dilator.

(a) ***Identification.*** A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

(b) ***Classification.*** Class II (performance standards).

§ 870.4500 Cardiovascular surgical instruments.

(a) ***Identification.*** Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989; 66 FR 38797, July 25, 2001]

§ 870.4510 Apical closure device.

(a) ***Identification.*** An apical closure device is a prescription device consisting of a delivery system and implant component that is used for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) The patient contacting materials must be evaluated to be biocompatible.

(2) Performance data must validate the sterility of the patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(4) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Consistent and reliable implant deployment;

(ii) Assessment of implant pull-out force; and

(iii) Sheath size compatibility with implant.

(5) In vivo evaluation of the device must demonstrate device performance, including device operation resulting in closure of the myocardial wound.

(6) Labeling must include the following:

(i) Detailed information explaining how the device operates;

(ii) Sheath size that device can accommodate;

(iii) Identification of the minimum myocardial wall thickness to ensure optimal device function; and

(iv) A shelf life.

[81 FR 71371, Oct. 17, 2016]

§ 870.4875 Intraluminal artery stripper.

(a) ***Identification.*** An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriscleroticarteries.)

(b) ***Classification.*** Class II (performance standards).

§ 870.4885 External vein stripper.

(a) ***Identification.*** An external vein stripper is an extravascular device used to remove a section of a vein.

(b) ***Classification.*** Class II (performance standards).

Subpart F—Cardiovascular Therapeutic Devices

§ 870.5050 Patient care suction apparatus.

(a) ***Identification.*** A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

(b) ***Classification.*** Class II (performance standards).

§ 870.5100 Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.

(a) ***Standard PTCA Catheter*** —

(1) ***Identification.*** A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

(2) ***Classification.*** Class II (special controls). The special control for this device is "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters." See § 870.1(e) for the availability of this guidance document.

(b) ***Cutting/scoring PTCA Catheter*** —

(1) ***Identification.*** A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

(2) ***Classification.*** Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 870.3.

[75 FR 54496, Sept. 8, 2010]

§ 870.5150 Embolectomy catheter.

(a) ***Identification.*** An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.

(b) ***Classification.*** Class II (performance standards).

§ 870.5175 Septostomy catheter.

(a) ***Identification.*** A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of certain infants.

(b) ***Classification.*** Class II (performance standards).

§ 870.5200 External cardiac compressor.

(a) ***Identification.*** An external cardiac compressor is an externally applied prescription device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest. External cardiac compressor devices are used as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (*e.g.,* during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Nonclinical performance testing under simulated physiological conditions must demonstrate the reliability of the delivery of specific compression depth and rate over the intended duration of use.

(2) Labeling must include the following:

(i) The clinical training necessary for the safe use of this device;

(ii) Adjunctive use only indication prominently displayed on labels physically placed on the device and in any device manuals or other labeling;

(iii) Information on the patient population for which the device has been demonstrated to be effective (including patient size and/or age limitations, *e.g.,* adult, pediatric and/or infant); and

(iv) Information on the time necessary to deploy the device as demonstrated in the performance testing.

(3) For devices that incorporate electrical components, appropriate analysis and testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(4) Human factors testing and analysis must validate that the device design and labeling are sufficient for effective use by the intended user, including an evaluation for the time necessary to deploy the device.

(5) For devices containing software, software verification, validation, and hazard analysis must be performed.

(6) Components of the device that come into human contact must be demonstrated to be biocompatible.

[81 FR 33133, May 25, 2016]

§ 870.5210 Cardiopulmonary resuscitation (CPR) aid.

(a) ***CPR aid without feedback*** —

(1) ***Identification.*** A CPR aid without feedback is a device that performs a simple function such as proper hand placement and/or simple prompting for rate and/or timing of compressions/breathing for the professionally trained rescuer, but offers no feedback related to the quality of the CPR being provided. These devices are intended for use by persons professionally trained in CPR to assure proper use and the delivery of optimal CPR to the victim.

(2) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

(b) ***CPR aid with feedback*** —

(1) ***Identification.*** A CPR Aid device with feedback is a device that provides real-time feedback to the rescuer regarding the quality of CPR being delivered to the victim, and provides either audio and/or visual information to encourage the rescuer to continue the consistent application of effective manual CPR in accordance with current accepted CPR guidelines (to include, but not be limited to, parameters such as compression rate, compression depth, ventilation, recoil, instruction for one or multiple rescuers, etc.). These devices may also perform a coaching function to aid rescuers in the sequence of steps necessary to perform effective CPR on a victim.

(2) ***Classification.*** Class II (special controls). The special controls for this device are:

(i) Nonclinical performance testing under simulated physiological or use conditions must demonstrate the accuracy and reliability of the feedback to the user on specific compression rate, depth and/or respiration over the intended duration, and environment of use.

(ii) Labeling must include the clinical training, if needed, for the safe use of this device and information on the patient population for which the device has been demonstrated to be effective (including patient size and/or age limitations, *e.g.,* adult, pediatric and/or infant).

(iii) For devices that incorporate electrical components, appropriate analysis and testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(iv) For devices containing software, software verification, validation, and hazard analysis must be performed.

(v) Components of the device that come into human contact must be demonstrated to be biocompatible.

(vi) Human factors testing and analysis must validate that the device design and labeling are sufficient for effective use by the intended user.

(3) ***Premarket notification.*** The CPR Aid with feedback device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if it does not contain software (*e.g.,* is mechanical or electro-mechanical) and is in compliance with the special controls under paragraph (b)(2) of this section, subject to the limitations of exemptions in § 870.9.

[81 FR 33134, May 25, 2016]

§ 870.5225 External counter-pulsating device.

(a) ***Identification.*** An external counter-pulsating device is a noninvasive, prescription device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle.

(b) ***Classification.***

(1) Class II (special controls) when the device is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. The special controls for this device are:

(i) Nonclinical performance evaluation of the device must demonstrate a reasonable assurance of safety and effectiveness for applied pressure, synchronization of therapy with the appropriate phase of the cardiac cycle, and functionality of alarms during a device malfunction or an abnormal patient condition;

(ii) Reliabilities of the mechanical and electrical systems must be established through bench testing under simulated use conditions and matched by appropriate maintenance schedules;

(iii) Software design and verification and validation must be appropriately documented;

(iv) The skin-contacting components of the device must be demonstrated to be biocompatible;

(v) Appropriate analysis and testing must be conducted to verify electrical safety and electromagnetic compatibility of the device; and

(vi) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to use of the device.

(2) Class III (premarket approval) for the following intended uses: Unstable angina pectoris; acute myocardial infarction; cardiogenic shock; congestive heart failure; postoperative treatment of patients who have undergone coronary artery bypass surgery; peripheral arterial disease associated with ischemic ulcers rest pain or claudication, threatened gangrene, insufficient blood supply at an

amputation site, persisting ischemia after embolectomy or bypass surgery, and/or pre- and post-arterial reconstruction to improve runoff; diabetes complicated by peripheral arterial disease or other conditions possibly related to arterial insufficiency including nocturnal leg cramps and/or necrobiosis diabeticorum; venous diseases, including prophylaxis of deep vein thrombophlebitis, edema (e.g., chronic lymphedema) and/or induration (e.g., stasis dermatitis) associated with chronic venous stasis, venous stasis ulcers, and/or thrombophlebitis; athletic injuries, including Charley horses, pulled muscles and/or edematous muscles; necrotizing cellulitis.

(c) ***Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.*** A PMA or notice of completion of a PDP is required to be filed with FDA on or before March 31, 2014, for any external counter-pulsating device, with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 31, 2014, been found to be substantially equivalent to any external counter-pulsating device, with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other external counter-pulsating device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[78 FR 79307, Dec. 30, 2013]

§ 870.5300 DC-defibrillator (including paddles).

(a) ***Low-energy DC-defibrillator*** —

(1) ***Identification.*** A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) ***Classification.*** Class II (performance standards).

(b) ***High-energy DC-defibrillator*** —

(1) ***Identification.*** A high-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) ***Classification.*** Class III (premarket approval).

(c) ***Date PMA or notice of completion of a PDP is required.*** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a DC-defibrillator (including paddles) described in paragraph (b)(1) of this

section that was in commercial distribution before May 28, 1976. Any other DC-defibrillator (including paddles) described in paragraph (b)(1) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.5310 Automated external defibrillator system.

(a) ***Identification.*** An automated external defibrillator (AED) system consists of an AED and those accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock (*e.g.,* battery, pad electrode, adapter, and hardware key for pediatric use). An AED system analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) ***Classification.*** Class III (premarket approval)

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA will be required to be submitted to the Food and Drug Administration by April 29, 2015, for any AED that was in commercial distribution before May 28, 1976, or that has, by April 29, 2015, been found to be substantially equivalent to any AED that was in commercial distribution before May 28, 1976. A PMA will be required to be submitted to the Food and Drug Administration by April 29, 2015, for any AED accessory described in paragraph (a) that was in commercial distribution before May 28, 1976, or that has, by April 29, 2015, been found to be substantially equivalent to any AED accessory described in paragraph (a) that was in commercial distribution before May 28, 1976. Any other AED and AED accessory described in paragraph (a), shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[68 FR 61344, Oct. 28, 2003; 69 FR 10615, Mar. 8, 2004, as amended at 80 FR 5682, Feb. 3, 2015]

§ 870.5325 Defibrillator tester.

(a) ***Identification.*** A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

(b) ***Classification.*** Class II (performance standards).

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) ***Identification.*** An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

(b) ***Classification.*** Class II. The special controls for this device are:

(1) "American National Standards Institute/American Association for Medical Instrumentation's DF-21 'Cardiac Defibrillator Devices' " 2d ed., 1996, and

(2) "The maximum pulse amplitude should not exceed 200 milliamperes. The maximum pulse duration should not exceed 50 milliseconds."

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 870.5600 Adjunctive open loop fluid therapy recommender.

(a) ***Identification.*** The adjunctive open loop fluid therapy recommender is a prescription device that uses software algorithms to analyze cardiovascular vital signs and predict a patient's estimated response to fluid therapy. The device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing under anticipated conditions of use must fulfill the following:

(i) A summary of the clinical performance testing must include the relevant patient demographics, and any statistical techniques used for analyzing the data;

(ii) Subjects must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified;

(iii) Testing must demonstrate the recommendation consistency using the expected range of data sources and data quality encountered in the intended patients, users, and environments; and

(iv) Testing must evaluate the relationship between algorithm recommendations, therapeutic actions, and predicted physiological event or status.

(2) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must be provided, including:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) A description of the expected recommendation, accounting for differences in patient condition and environment;

(iii) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) that affect the device's recommendations;

(iv) A characterization of algorithm sensitivity to variations in user inputs;

(v) A characterization of sensor accuracy and performance;

(vi) A description of sensor data quality control measures; and

(vii) Safeguards to reduce the possibility of fluid overload.

(3) A scientific justification for the validity of the algorithm(s) must be provided. This justification must include non-clinical verification and validation of the algorithm calculations and clinical validation using an independent data set.

(4) A human factors and usability engineering assessment must be provided.

(5) Labeling must include:

(i) A description of what the device measures, how the device decides to issue recommendations, and the expected range of frequency of recommendations, while accounting for differences in patient condition and environment;

(ii) Detailed information regarding limitations of the device's algorithm, and key assumptions made when the device issues a recommendation;

(iii) Warnings identifying sensor acquisition factors that may impact measurement results;

(iv) Warnings identifying user errors that affect the device's recommendations;

(v) Detailed information regarding the expected impact of user input errors on the device recommendations;

(vi) Guidance for interpretation of the device's recommendations, including a description that the recommendation is adjunctive to other physical vital sign parameters and patient information;

(vii) Description of the impact of the compatible sensor(s) on the device's performance;

(viii) The expected performance of the device for all intended patients, users, and environments;

(ix) Relevant characteristics of the patients studied in the clinical validation (such as age, gender, race or ethnicity, and patient condition) and a summary of validation results; and

(x) Description of the software safeguards that are in place to prevent fluid overload, and description of any limitation of the software safeguards.

[89 FR 72319, Sept. 5, 2024]

§ 870.5700 Steerable cardiac ablation catheter remote control system.

(a) ***Identification.*** A steerable cardiac ablation catheter remote control system is a prescription device that is external to the body and interacts with the manual handle of a steerable cardiac ablation catheter to remotely control the advancement, retraction, rotation, and deflection of a compatible, steerable ablation catheter used for the treatment of cardiac arrhythmias in the right side of the heart. The device allows reversion to manual control of the steerable cardiac ablation catheter without withdrawal of the catheter and interruption of the procedure.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Non-clinical mechanical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be performed:

(i) Mechanical performance of the system (without catheter connected);

(ii) Mechanical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:

(A) Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and

(B) Evaluation of the accuracy and function of all device control safety features; and

(iii) Simulated-use testing in a bench anatomic model or animal model.

(2) Non-clinical electrical testing must include validation of electromagnetic compatibility (EMC), electrical safety, thermal safety, and electrical system performance. The following performance testing must be performed:

(i) Electrical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:

(A) Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and

(B) Evaluation of the accuracy and function of all device control safety features; and

(ii) Electrical safety between the device and ablation catheter system and with other electrical equipment expected in the catheter lab or operating room.

(3) In vivo testing must demonstrate that the device performs as intended under anticipated conditions of use, including an assessment of the system impact on the functionality and performance of compatible catheters, and documentation of the adverse event profile associated with clinical use. Evidence must be submitted to address the following:

(i) Manipulation and Positioning: Ability to manipulate compatible catheters to pre-specified cardiac locations and confirm proper anatomic placement and tissue contact, in accordance with the system indications for use and the compatible catheter indications for use;

(ii) Safety: Assess device-related complication rate and major procedural complication rate (regardless of device relatedness) in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use;

(iii) Efficacy: Assess ablation success in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use; and

(iv) User assessment of device remote controls and safety features.

(4) Post-market surveillance (PMS) must be conducted and completed in accordance with FDA agreed upon PMS protocol.

(5) A training program must be included with sufficient educational elements that, upon completion of the training program, the clinician and supporting staff can:

(i) Identify the safe environments for device use,

(ii) Use all safety features of device, and

(iii) Operate the device in simulated or actual use environments representative of indicated environments and use for the indication of compatible catheters.

(6) Performance data must demonstrate the sterility of the sterile disposable components of the system.

(7) Performance data must support shelf life by demonstrating continued sterility of the device (of the sterile disposable components), package integrity, and device functionality over the requested shelf life.

(8) Labeling must include the following:

(i) Appropriate instructions, warnings, cautions, limitations, and information related to the intended patient population, compatible ablation catheters, and the device safeguards for the safe use of the device;

(ii) Specific instructions and the clinical training needed for the safe use of the device, which includes:

(A) Instructions on assembling the device in all available configurations, including installation and removal of compatible catheters;

(B) Instructions and explanation of all controls, inputs, and outputs;

(C) Instructions on all available modes or states of the device;

(D) Instructions on all safety features of the device; and

(E) Validated methods and instructions for reprocessing/disinfecting any reusable components;

(iii) A detailed summary of the mechanical compatibility testing including:

(A) A table with a complete list of compatible catheters tested (manufacturer trade name and model number), and

(B) A table with detailed test results, including type of test, acceptance criteria, and test results (*i.e.,* pass for meeting acceptance criteria);

(iv) A detailed summary of the in vivo testing including:

(A) A table with a complete list of compatible catheters used during testing (manufacturer trade name and model number);

(B) Adverse events encountered pertinent to use of the device under use conditions;

(C) A detailed summary of the device- and procedure-related complications; and

(D) A summary of study outcomes and endpoints. Information pertinent to the fluoroscopy times/exposure for the procedure, patient, and operator fluoroscopic exposure;

(v) Other labeling items:

(A) A detailed summary of pertinent non-clinical testing information: EMC, mechanical, electrical, and sterilization of device and components;

(B) A detailed summary of the device technical parameters; and

(C) An expiration date/shelf life and storage conditions for the sterile accessories; and

(vi) When available, and according to the timeframe included in the PMS protocol agreed upon with FDA, provide a detailed summary of the PMS data including:

(A) Updates to the labeling to accurately reflect outcomes or necessary modifications based upon data collected during the PMS experience, and

(B) Inclusion of results and adverse events associated with utilization of the device during the PMS.

[80 FR 58606, Sept. 30, 2015]

§ 870.5800 Compressible limb sleeve.

(a) ***Identification.*** A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

(b) ***Classification.*** Class II (performance standards).

§ 870.5900 Thermal regulating system.

(a) ***Identification.*** A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.

(b) ***Classification.*** Class II (performance standards).

§ 870.5910 Esophageal thermal regulation device.

(a) ***Identification.*** An esophageal thermal regulation device is a prescription device used to apply a specified temperature to the endoluminal surface of the esophagus via an external controller. This device may incorporate a mechanism for gastric decompression and suctioning. The device is used to regulate patient temperature.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) The patient contacting materials must be demonstrated to be biocompatible.

(2) Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical integrity testing.

(ii) Testing to determine temperature change rate(s).

(iii) Testing to demonstrate compatibility with the indicated external controller.

(iv) Shelf life testing.

(3) Animal testing must demonstrate that the device does not cause esophageal injury and that body temperature remains within appropriate boundaries under anticipated conditions of use.

(4) Labeling must include the following:

(i) Detailed insertion instructions.

(ii) Warning against attaching the device to unintended connections, such as external controllers for which the device is not indicated, or pressurized air outlets instead of vacuum outlets for those devices, including gastric suction.

(iii) The operating parameters, name, and model number of the indicated external controller.

(iv) The intended duration of use.

[80 FR 49896, Aug. 18, 2015]

§ 870.5925 Automatic rotating tourniquet.

(a) ***Identification.*** An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

(b) ***Classification.*** Class II (performance standards).