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

PART 890—PHYSICAL MEDICINE DEVICES

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

Source: 48 FR 53047, Nov. 23, 1983, unless otherwise noted.

Editorial Note: Nomenclature changes to part 890 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine 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 physical medicine 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 17741, May 11, 1987, as amended at 73 FR 34860, June 19, 2008; 78 FR 18233, Mar. 26, 2013]

§ 890.3 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 of 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, includiing 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 17741, May 11, 1987]

§ 890.9 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 2321, Jan. 14, 2000]

Subpart B—Physical Medicine Diagnostic Devices

§ 890.1175 Electrode cable.

(a) ***Identification.*** An electrode cable is a device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.

(b) ***Classification.*** Class II (special controls). The special controls consist of:

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

(2) The guidance document entitled "Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables." This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 65 FR 19319, Apr. 11, 2000]

§ 890.1225 Chronaximeter.

(a) ***Identification.*** A chronaximeter is a device intended for medical purposes to measure neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.

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

§ 890.1375 Diagnostic electromyograph.

(a) ***Identification.*** A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.

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

§ 890.1385 Diagnostic electromyograph needle electrode.

(a) ***Identification.*** A diagnostic electromyograph needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medical purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle).

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

§ 890.1450 Powered reflex hammer.

(a) ***Identification.*** A powered reflex hammer is a motorized device intended for medical purposes to elicit and determine controlled deep tendon reflexes.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

§ 890.1575 Force-measuring platform.

(a) ***Identification.*** A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§ 890.1600 Intermittent pressure measurement system.

(a) ***Identification.*** An intermittent pressure measurement system is an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§ 890.1615 Miniature pressure transducer.

(a) ***Identification.*** A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§ 890.1850 Diagnostic muscle stimulator.

(a) ***Identification.*** A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity. It is intended for medical purposes, such as to diagnose motor nerve or sensory neuromuscular disorders and neuromuscular function.

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

§ 890.1925 Isokinetic testing and evaluation system.

(a) ***Identification.*** An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59230, Nov. 3, 1998]

Subpart C [Reserved]

Subpart D—Physical Medicine Prosthetic Devices

§ 890.3025 Prosthetic and orthotic accessory.

(a) ***Identification.*** A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3050 External compression device for internal jugular vein compression.

(a) ***Identification.*** An external compression device for internal jugular vein compression is a non-invasive device that is intended to increase intracranial blood volume to reduce the occurrence of specific changes in the brain following head impacts sustained from the environment of use.

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

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

(2) Performance testing must demonstrate that the device performs as intended under anticipated conditions of use for the duration of the labeled use life.

(3) Human factors and usability testing must demonstrate that users can correctly use the device, including the user's ability to correctly determine device size and confirm the proper fit of the device. Users must understand product limitations, warnings, and precautions, including the warning that the device does not prevent head injury and medical treatment should be sought following head injury.

(4) Labeling must include the following:

(i) A warning that the device does not replace, and should be worn with, other protective sports equipment associated with specific sports activities, such as helmets and shoulder pads;

(ii) A warning that the device should not be worn if it interferes with other existing protective equipment;

(iii) A warning that users should avoid head and neck impacts to the extent possible;

(iv) A warning that serious harm can result from persistent, excessive pressure on the neck due to incorrect device size and fit; and

(v) A warning that the device has not been demonstrated to prevent long-term cognitive function deficits, and the ultimate impact on clinical outcomes has not been evaluated.

[89 FR 71160, Sept. 3, 2024]

§ 890.3075 Cane.

(a) ***Identification.*** A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3100 Mechanical chair.

(a) ***Identification.*** A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38816, July 25, 2001]

§ 890.3110 Electric positioning chair.

(a) ***Identification.*** An electric positioning chair is a device with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.

(b) ***Classification.*** Class II. The electric positioning chair is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9 and the following conditions for exemption:

(1) Appropriate analysis and non-clinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and non-clinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and non-clinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device;

(4) Appropriate analysis and non-clinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ANSI/AAMI/ES60601-1, "Medical Electrical Equipment—Part 1: General Requirements for Basic Safety and Essential Performance," and ANSI/AAMI/IEC 60601-1-2, "Medical Electrical Equipment—Part 1-2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests") must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process," ANSI/AAMI/ISO 10993-5, "Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity," and ANSI/AAMI/ISO 10993-10, "Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Skin Sensitization") must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of IEC 62304, "Medical Device Software—Software Life Cycle Processes") must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and non-clinical testing must validate that the device components are found to be non-flammable;

(9) Appropriate analysis and non-clinical testing must validate that the battery in the device (if applicable) performs as intended over the anticipated service life of the device; and

(10) Adequate patient labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device by the patient in the intended use environment.

[48 FR 53047, Nov. 23, 1983, as amended at 80 FR 72950, Nov. 20, 2015]

§ 890.3150 Crutch.

(a) ***Identification.*** A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3175 Flotation cushion.

(a) ***Identification.*** A flotation cushion is a device intended for medical purposes that is made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§ 890.3410 External limb orthotic component.

(a) ***Identification.*** An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3420 External limb prosthetic component.

(a) ***Identification.*** An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3450 Upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components.

(a) ***Identification.*** A upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.

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

(1) Appropriate analysis/testing must validate electronic compatibility, electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

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

(3) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

(i) Mechanical bench data, including durability testing, to demonstrate that the device will withstand forces, conditions, and environments encountered during use.

(ii) Simulated use testing to demonstrate performance of arm commands and available safeguard(s) under worst case conditions and after durability testing.

(iii) Verification and validation of force sensors and hand release button, if applicable, are necessary.

(iv) Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor and brake performance.

(v) The accuracy of the device features and safeguards.

(4) Non-clinical and clinical performance testing must demonstrate the accuracy of device features and safeguards.

(5) Elements of the device that may contact the patient must be demonstrated to be biocompatible.

(6) Documented clinical experience and human factors testing must demonstrate safe and effective use, capture any adverse events observed during clinical use and demonstrate the accuracy of device features and safeguards.

(7) Labeling for the Prosthetist and User Guide must include:

(i) Appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities that may put the user at greater risk (*e.g.,* driving).

(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,

(B) Instructions on fitting the patient,

(C) Instructions and explanations of all available programs and how to program the device,

(D) Instructions and explanation of all controls, input, and outputs,

(E) Instructions on all available modes or states of the device,

(F) Instructions on all safety features of the device, and

(G) Instructions for maintaining the device.

(iii) Information on the patient population for which the device has been demonstrated to be effective.

(iv) A detailed summary of the non-clinical and clinical testing pertinent to use of the device.

[81 FR 71612, Oct. 18, 2016]

§ 890.3475 Limb orthosis.

(a) ***Identification.*** A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3480 Powered lower extremity exoskeleton.

(a) ***Identification.*** A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.

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

(1) Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.

(2) Appropriate analysis/testing must validate electromagnetic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

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

(4) Design characteristics must ensure geometry and materials composition are consistent with intended use.

(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

(i) Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions, and environments encountered during use;

(ii) Simulated use testing (*i.e.,* cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing;

(iii) Verification and validation of manual override controls are necessary, if present;

(iv) The accuracy of device features and safeguards; and

(v) Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.

(6) Clinical testing must demonstrate a reasonable assurance of safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:

(i) Level of supervision necessary, and

(ii) Environment of use (*e.g.,* indoors and/or outdoors) including obstacles and terrain representative of the intended use environment.

(7) A training program must be included with sufficient educational elements so that upon completion of training program, the clinician, user, and companion 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.

(8) Labeling for the Physician and User must include the following:

(i) Appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk.

(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;

(B) Instructions on fitting the patient;

(C) Instructions and explanations of all available programs and how to program the device;

(D) Instructions and explanation of all controls, input, and outputs;

(E) Instructions on all available modes or states of the device;

(F) Instructions on all safety features of the device; and

(G) Instructions for properly maintaining the device.

(iii) Information on the patient population for which the device has been demonstrated to have a reasonable assurance of safety and effectiveness.

(iv) Pertinent non-clinical testing information (*e.g.,* EMC, battery longevity).

(v) A detailed summary of the clinical testing including:

(A) Adverse events encountered under use conditions,

(B) Summary of study outcomes and endpoints, and

(C) Information pertinent to use of the device including the conditions under which the device was studied (*e.g.,* level of supervision or assistance, and environment of use (*e.g.,* indoors and/or outdoors) including obstacles and terrain).

[80 FR 25529, May 4, 2015]

§ 890.3490 Truncal orthosis.

(a) ***Identification.*** A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3500 External assembled lower limb prosthesis.

(a) ***Identification.*** An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.3520 Plinth.

(a) ***Identification.*** A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.3610 Rigid pneumatic structure orthosis.

(a) ***Identification.*** A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.

(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 rigid pneumatic structure orthosis 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 rigid pneumatic structure

orthosis that was in commercial distribution before May 28, 1976. Any other rigid pneumatic structure orthosis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 61 FR 50711, Sept. 27, 1996]

§ 890.3640 Arm sling.

(a) ***Identification.*** An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.3665 Congenital hip dislocation abduction splint.

(a) ***Identification.*** A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.3675 Denis Brown splint.

(a) ***Identification.*** A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.3690 Powered wheeled stretcher.

(a) ***Identification.*** A powered wheeled stretcher is a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).

(b) ***Classification.*** Class II (performance standards). The powered wheeled stretcher is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9, and the following conditions for exemption:

(1) Appropriate analysis and nonclinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and nonclinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device;

(4) Appropriate analysis and nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable;

(9) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device;

(10) Adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and

(11) Appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds, and mitigation strategy to reduce entrapment.

[48 FR 53047, Nov. 23, 1983, as amended at 85 FR 2020, Jan. 14, 2020]

§ 890.3700 Nonpowered communication system.

(a) ***Identification.*** A nonpowered communication system is a mechanical device intended for medical purposes that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include an alphabet board and a page turner.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 54 FR 25052, June 12, 1989; 66 FR 38817, July 25, 2001]

§ 890.3710 Powered communication system.

(a) ***Identification.*** A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include the following: a specialized typewriter, a reading machine, and a video picture and word screen.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.3725 Powered environmental control system.

(a) ***Identification.*** A powered environmental control system is an AC- or battery-powered device intended for medical purposes that is used by a patient to operate an environmental control function. Examples of environmental control functions include the following: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.3750 Mechanical table.

(a) ***Identification.*** A mechanical table is a device intended for medical purposes that has a flat surface that can be inclined or adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

§ 890.3760 Powered table.

(a) ***Identification.*** A powered table is a device intended for medical purposes that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38817, July 25, 2001]

§ 890.3790 Cane, crutch, and walker tips and pads.

(a) ***Identification.*** Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories intended for medical purposes that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.3800 Motorized three-wheeled vehicle.

(a) ***Identification.*** A motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled persons.

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

§ 890.3825 Mechanical walker.

(a) ***Identification.*** A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.3850 Mechanical wheelchair.

(a) ***Identification.*** A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) ***Classification.*** Class I (general controls).

§ 890.3860 Powered wheelchair.

(a) ***Identification.*** A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

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

§ 890.3880 Special grade wheelchair.

(a) ***Identification.*** A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.

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

§ 890.3890 Stair-climbing wheelchair.

(a) ***Identification.*** A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.

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

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:

(i) Fatigue testing;

(ii) Resistance to dynamic loads (impact testing);

(iii) Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;

(iv) Demonstration of adequate stability of the device on inclined planes (forward, backward, and lateral);

(v) Demonstration of the ability of the device to safely ascend and descend obstacles (i.e., stairs, curb); and

(vi) Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.

(3) The skin-contacting components of the device must be demonstrated to be biocompatible.

(4) Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.

(5) Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(6) Performance testing must demonstrate battery safety and evaluate longevity.

(7) Performance testing must evaluate the flammability of device components.

(8) Patient labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device and the principles of how the device works;

(ii) A clear description of the appropriate use environments/conditions, including prohibited environments;

(iii) Preventive maintenance recommendations;

(iv) Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and

(v) A detailed summary of the device-related adverse events and how to report any complications.

(9) Clinician labeling must include all the information in the Patient labeling noted in paragraph (b)(8) of this section but must also include the following:

(i) Identification of patients who can effectively operate the device; and

(ii) Instructions on how to fit, modify, or calibrate the device.

(10) Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

[79 FR 20782, Apr. 14, 2014]

§ 890.3900 Standup wheelchair.

(a) ***Identification.*** A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.

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

§ 890.3910 Wheelchair accessory.

(a) ***Identification.*** A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.

(b) ***Classification.*** Class I (general controls). If the device is not intended for use as a protective restraint as defined in § 880.6760 of this chapter, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[61 FR 8439, Mar. 4, 1996, as amended at 66 FR 38817, July 25, 2001]

§ 890.3920 Wheelchair component.

(a) ***Identification.*** A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

§ 890.3930 Wheelchair elevator.

(a) ***Permanently mounted wheelchair platform lift*** —

(1) ***Identification.*** A permanently mounted wheelchair platform lift is a motorized vertical or inclined platform lift device permanently installed in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by providing a guided platform to move a person from one level to another, with or without a wheelchair.

(2) ***Classification.*** Class II. The permanently mounted wheelchair platform lift is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9 and the following conditions for exemption:

(i) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must demonstrate that the safety controls are adequate to prevent a free fall of the platform in the event of a device failure;

(ii) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must demonstrate the ability of the device to withstand the rated load with an appropriate factor of safety;

(iii) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must demonstrate the ability of the enclosures to prevent the user from falling from the device; and

(iv) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized editions of AAMI/ANSI/IEC 60601-1-2, “Medical Electrical Equipment—Part 1-2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests,” and ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must validate electromagnetic compatibility and electrical safety.

(b) ***Portable wheelchair elevators*** —

(1) ***Identification.*** A portable wheelchair elevator is a motorized lift device that is not permanently mounted in one location and that is intended for use in mitigating mobility impairment caused by injury or other disease by providing a means to move a person, with or without a wheelchair, from one level to another (e.g., portable platform lifts, attendant-operated stair climbing devices for wheelchairs).

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

[78 FR 14015, Mar. 4, 2013]

§ 890.3940 Wheelchair platform scale.

(a) ***Identification.*** A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended for medical purposes to weigh a person who is confined to a wheelchair.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

Subpart E [Reserved]

Subpart F—Physical Medicine Therapeutic Devices

§ 890.5050 Daily activity assist device.

(a) ***Identification.*** A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.

(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 § 890.9. If the device is not labeled or otherwise represented as sterile, the device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.5100 Immersion hydrobath.

(a) ***Identification.*** An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(b) ***Classification.*** Class II (special controls). The device, when it is a hydromassage bath or a powered sitz bath, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

§ 890.5110 Paraffin bath.

(a) ***Identification.*** A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the patient's appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

§ 890.5125 Nonpowered sitz bath.

(a) ***Identification.*** A nonpowered sitz bath is a device intended for medical purposes that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 54 FR 25052, June 12, 1989; 66 FR 38818, July 25, 2001]

§ 890.5150 Powered patient transport.

(a) ***Powered patient stairway chair lifts*** —

(1) ***Identification.*** A powered patient stairway chair lift is a motorized lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.

(2) ***Classification.*** Class II. The stairway chair lift is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9 and the following conditions for exemption:

(i) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of American Society of Mechanical Engineers (ASME) A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must demonstrate that the safety controls are adequate to prevent a free fall of the chair in the event of a device failure;

(ii) Appropriate analysis and nonclinical testing must demonstrate the ability of the device, including armrests, to withstand the rated load with an appropriate factor of safety;

(iii) Appropriate restraints must be provided to prevent the user from falling from the device (such as that outlined in the currently FDA-recognized edition of ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”);

(iv) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized editions of AAMI/ANSI/IEC 60601-1-2, "Medical Electrical Equipment—Part 1-2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests," and ASME A18.1 "Safety Standard for Platform Lifts and Stairway Chair Lifts") must validate electromagnetic compatibility and electrical safety; and

(v) Appropriate analysis and nonclinical testing must demonstrate the resistance of the device upholstery to ignition.

(b) ***All other powered patient transport*** —

(1) ***Identification.*** A powered patient transport is a motorized device intended for use in mitigating mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs (e.g., attendant-operated portable stair-climbing chairs). This generic type of device does not include motorized three-wheeled vehicles or wheelchairs.

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

[78 FR 14017, Mar. 4, 2013]

§ 890.5160 Air-fluidized bed.

(a) ***Identification.*** An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5170 Powered flotation therapy bed.

(a) ***Identification.*** A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5180 Manual patient rotation bed.

(a) ***Identification.*** A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1963, as amended at 65 FR 2322, Jan. 14, 2000]

§ 890.5225 Powered patient rotation bed.

(a) ***Identification.*** A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, urinary tract blockage, and to aid circulation.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5250 Moist steam cabinet.

(a) ***Identification.*** A moist steam cabinet is a device intended for medical purposes that delivers a flow of heated, moisturized air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

§ 890.5275 Microwave diathermy.

(a) ***Microwave diathermy for use in applying therapeutic deep heat for selected medical conditions*** —

(1) ***Identification.*** A microwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

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

(b) ***Microwave diathermy for all other uses*** —

(1) ***Identification.*** A microwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

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

(c) ***Date PMA or notice of completion of PDP is required.*** A PMA or a notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999, for any microwave diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a microwave diathermy described in paragraph (b) of this

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

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 64 FR 18331, Apr. 14, 1999]

§ 890.5290 Shortwave diathermy.

(a) ***Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions*** —

(1) ***Identification.*** A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radiofrequency (RF) bands of 13.56 megahertz (MHz) or 27.12 MHz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

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

(b) ***Nonthermal shortwave therapy*** —

(1) ***Identification.*** A nonthermal shortwave therapy is a prescription device that applies to the body pulsed electromagnetic energy in the RF bands of 13.56 MHz or 27.12 MHz and that is intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

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

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

(ii) Appropriate analysis/testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(iii) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Non-clinical performance testing must characterize the output waveform of the device and demonstrate that the device meets appropriate output performance specifications. The output characteristics and the methods used to determine these characteristics, including the following, must be determined:

(A) Peak output power;

(B) Pulse width;

(C) Pulse frequency;

(D) Duty cycle;

(E) Characteristics of other types of modulation that may be used;

(F) Average measured output powered into the RF antenna/applicator;

(G) Specific absorption rates in saline gel test load or other appropriate model;

(H) Characterization of the electrical and magnetic fields in saline gel test load or other appropriate model for each RF antenna and prescribed RF antenna orientation/position; and

(I) Characterization of the deposited energy density in saline gel test load or other appropriate model.

(iv) A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device in its intended use.

(v) Labeling must include the following:

(A) Output characteristics of the device;

(B) Recommended treatment regimes, including duration of use; and

(C) A detailed summary of the clinical testing pertinent to the use of the device and a summary of the adverse events and complications.

(vi) Nonthermal shortwave therapy devices marketed prior to the effective date of this reclassification must submit an amendment to their previously cleared premarket notification (510(k)) demonstrating compliance with these special controls.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 80 FR 61302, Oct. 13, 2015]

§ 890.5300 Ultrasonic diathermy.

(a) ***Ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions*** —

(1) ***Identification.*** An ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

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

(b) ***Ultrasonic diathermy for all other uses*** —

(1) ***Identification.*** An ultrasonic diathermy for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(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 for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999, for any ultrasonic diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasonic diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasonic diathermy described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 64 FR 18331, Apr. 14, 1999]

§ 890.5350 Exercise component.

(a) ***Identification.*** An exercise component is a device that is used in conjunction with other forms of exercise and that is intended for medical purposes, such as to redevelope muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38818, July 25, 2001]

§ 890.5360 Measuring exercise equipment.

(a) ***Identification.*** Measuring exercise equipment consist of manual devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes., Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.

(b) ***Classification.*** Class II (special controls). The device, when it is a measuring exerciser or an interactive rehabilitation exercise device for prescription use only, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019; 85 FR 44188, July 22, 2020]

§ 890.5370 Nonmeasuring exercise equipment.

(a) ***Identification.*** Nonmeasuring exercise equipment consist of devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38818, July 25, 2001]

§ 890.5380 Powered exercise equipment.

(a) ***Identification.*** Powered exercise equipment consist of powered devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5410 Powered finger exerciser.

(a) ***Identification.*** A powered finger exerciser is a device intended for medical purposes to increase flexion and the extension range of motion of the joints of the second to the fifth fingers of the hand.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5420 Electroencephalography (EEG)-driven upper extremity powered exerciser.

(a) ***Identification.*** An EEG-driven upper extremity powered exerciser is a non-invasive prescription device intended for rehabilitation by driving movement or exercise of an impaired upper extremity in response to the detection of purpose oriented electrical activity produced by the patient's brain.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must capture any adverse events observed during clinical use and must demonstrate that the EEG signal can be translated into intended motion.

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

(3) Performance data must demonstrate the electromagnetic compatibility, electrical safety, battery safety, and wireless compatibility of the device.

(4) The device components that contact the patient must be demonstrated to be biocompatible.

(5) Performance data must validate the reprocessing instructions for the reusable components of the device.

(6) Labeling must include:

(i) Instructions on fitting the device to the patient;

(ii) Information on how the device operates and the typical sensations experienced during treatment; and

(iii) Reprocessing instructions.

[88 FR 983, Jan. 6, 2023]

§ 890.5500 Infrared lamp.

(a) ***Identification.*** An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

(b) ***Classification.*** Class II (special controls). The device, when it is an infrared therapeutic heating lamp, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

§ 890.5525 Iontophoresis device.

(a) ***Iontophoresis device intended for certain specified uses*** —

(1) ***Identification.*** An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug. When used in the diagnosis of cystic fibrosis, the sweat is collected and its composition and weight are determined.

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

(b) ***Iontophoresis device intended for any other purposes*** —

(1) ***Identification.*** An iontophoresis device intended for any other purposes is a prescription device that is intended to use a current to introduce ions of drugs or non-drug solutions into the body for medical purposes other than those specified in paragraph (a) of this section, meaning that the device is not intended for use in diagnosis of cystic fibrosis, or a specific drug is not specified in the labeling of the iontophoresis device.

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

(i) The following performance testing must be conducted:

(A) Testing using a drug approved for iontophoretic delivery, or a solution if identified in the labeling, to demonstrate safe use of the device as intended;

(B) Testing of the ability of the device to maintain a safe pH level; and

(C) If used in the ear, testing of the device to demonstrate mechanical safety.

(ii) Labeling must include adequate instructions for use, including sufficient information for the health care provider to determine the device characteristics that affect delivery of the drug or solution and to select appropriate drug or solution dosing information for administration by iontophoresis. This includes the following:

(A) A description and/or graphical representation of the electrical output;

(B) A description of the electrode materials and pH buffer;

(C) When intended for general drug delivery, language referring the user to drug labeling approved for iontophoretic delivery to determine if the drug they intend to deliver is specifically approved for use with that type of device and to obtain relevant dosing information; and

(D) A detailed summary of the device-related and procedure-related complications pertinent to use of the device, and appropriate warnings and contraindications, including the following warning:

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

(iii) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.

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

(v) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(vi) The elements of the device that may contact the patient must be assessed for sterility, for devices labeled as sterile.

(vii) Performance data must support the shelf life of the elements of the device that may be affected by aging by demonstrating continued package integrity and device functionality over the stated shelf life.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 81 FR 48706, July 26, 2016; 83 FR 13864, Apr. 2, 2018]

§ 890.5575 Powered external limb overload warning device.

(a) ***Identification.*** A powered external limb overload warning device is a device intended for medical purposes to warn a patient of an overload or an underload in the amount of pressure placed on a leg.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

§ 890.5650 Powered inflatable tube massager.

(a) ***Identification.*** A powered inflatable tube massager is a powered device intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

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

§ 890.5660 Therapeutic massager.

(a) ***Identification.*** A therapeutic massager is an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5670 Internal therapeutic massager.

(a) ***Identification.*** A hand-held internal therapeutic massager device is a prescription device intended for medical purposes to manually provide direct pressure applied to localized areas of pain or tenderness in the myofascial tissue associated with chronic pelvic pain syndromes. The device is inserted rectally or vaginally and provides quantitative feedback to the user of the applied force to the target tissue.

(b) ***Classification.*** Class II (special controls). The device, when it is for prescription use only with a quantitative feedback mechanism and a disposable covering, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9. The special controls for this device are:

(1) Labeling must include adequate directions for use.

(2) Non-clinical performance testing must demonstrate electromagnetic compatibility (EMC), electrical safety and mechanical safety.

(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) Mechanical durability; and

(ii) Accuracy of the feedback mechanism.

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

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

[84 FR 57323, Oct. 25, 2019, as amended at 85 FR 44188, July 22, 2020]

§ 890.5700 Cold pack.

(a) ***Identification.*** A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.

(b) ***Classification.*** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5710 Hot or cold disposable pack.

(a) ***Identification.*** A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.

(b) ***Classification.*** Class I (general controls). Except when intended for use on infants, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1963, as amended at 65 FR 2322, Jan. 14, 2000]

§ 890.5720 Water circulating hot or cold pack.

(a) ***Identification.*** A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5730 Moist heat pack.

(a) ***Identification.*** A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38818, July 25, 2001]

§ 890.5740 Powered heating pad.

(a) ***Identification.*** A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) ***Classification.*** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5760 Nonpowered lower extremity pressure wrap.

(a) ***Identification.*** A nonpowered lower extremity pressure wrap is a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.

(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 § 890.9.

[79 FR 37950, July 3, 2014]

§ 890.5765 Pressure-applying device.

(a) ***Identification.*** A pressure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38818, July 25, 2001]

§ 890.5800 Virtual reality behavioral therapy device for pain relief.

(a) ***Identification.*** A virtual reality behavioral therapy device for pain relief is a device intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display that utilizes a software program containing the behavioral therapy content.

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

(1) Clinical performance testing under the labeled conditions for use must validate the model of behavioral therapy as implemented by the device and evaluate all adverse events.

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

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

(4) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(5) Labeling must include the following:

(i) A warning regarding the risk of nausea and motion sickness;

(ii) A warning regarding the risk of discomfort from the device; and

(iii) A summary of the clinical testing with the device.

[88 FR 985, Jan. 6, 2023]

§ 890.5850 Powered muscle stimulator.

(a) ***Identification.*** A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

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

§ 890.5860 Ultrasound and muscle stimulator.

(a) ***Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions*** —

(1) ***Identification.*** An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. The device also passes electrical currents through the body area to stimulate or relax muscles.

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

(b) ***Ultrasound and muscle stimulator for all other uses*** —

(1) ***Identification.*** An ultrasound and muscle stimulator for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and applies to the body electrical currents and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles as described in paragraph (a) of this section.

(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 for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasound and muscle stimulator described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 64 FR 18331, Apr. 14, 1999]

§ 890.5880 Multi-function physical therapy table.

(a) ***Identification.*** A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.

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

§ 890.5900 Power traction equipment.

(a) ***Identification.*** Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

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

§ 890.5925 Traction accessory.

(a) ***Identification.*** A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.

(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 § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5940 Chilling unit.

(a) ***Identification.*** A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.

(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 § 890.9

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5950 Powered heating unit.

(a) ***Identification.*** A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5975 Therapeutic vibrator.

(a) ***Identification.*** A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]