

## PART 880 GENERAL HOSPITAL AND PERSONAL USE DEVICES

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## Subpart A--General Provisions

### Sec. 880.1 Scope.

(a) This part sets forth the classification of general hospital and personal use 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 general hospital and personal use 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>.

### Sec. 880.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an

exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

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

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

## **Sec. 880.9 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).

## Subpart B [Reserved]

## Subpart C--General Hospital and Personal Use Monitoring Devices

### Sec. 880.2200 Liquid crystal forehead temperature strip.

(a) *Identification.* A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence



or absence of fever, or to monitor body temperature changes. The device displays the color changes of heat sensitive liquid crystals corresponding to the variation in the surface temperature of the skin. The liquid crystals, which are cholesteric esters, are sealed in plastic.

(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 880.9.

**Sec. 880.2400 Bed-patient monitor.**

(a) *Identification.* A bed-patient monitor is a battery-powered device placed under a mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.

(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 880.9.

**Sec. 880.2420 Electronic monitor for gravity flow infusion systems.**

(a) *Identification.* An electronic monitor for gravity flow infusion systems is a device used to monitor the amount of fluid being infused into a patient. The device consists of an electronic transducer and equipment for signal amplification, conditioning, and display.

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

**Sec. 880.2460 Electrically powered spinal fluid pressure monitor.**

(a) *Identification.* An electrically powered spinal fluid pressure monitor is an electrically powered device used to measure spinal fluid pressure by the use of a transducer which converts spinal fluid pressure into an electrical signal. The device includes signal amplification, conditioning, and display equipment.

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

**Sec. 880.2500 Spinal fluid manometer.**

(a) *Identification.* A spinal fluid manometer is a device used to measure spinal fluid pressure. The device uses a hollow needle, which is inserted into the spinal column fluid space, to connect the spinal fluid to a graduated column so that the pressure can be measured by reading the height of the fluid.

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

#### **Sec. 880.2700 Stand-on patient scale.**

(a) *Identification.* A stand-on patient scale is a device intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform.

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.2720 Patient scale.**

(a) *Identification.* A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scale. This generic device includes devices placed under a bed or chair to weigh both the support and the patient, devices where the patient is lifted by a sling from a bed to be weighed, and devices where the patient is placed on the scale platform to be weighed. The device may be mechanical, battery powered, or AC-powered and may include transducers, electronic signal amplification, conditioning and display

equipment.

(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 880.9.

#### **Sec. 880.2740 Surgical sponge scale.**

(a) *Identification*. A surgical sponge scale is a nonelectrically powered device used to weigh surgical sponges that have been used to absorb blood during surgery so that, by comparison with the known dry weight of the sponges, an estimate may be made of the blood lost by the patient during surgery.

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.2800 Sterilization process indicator.**

(a) *Biological sterilization process indicator* -- (1) *Identification*. A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the

adequacy of sterilization.

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

(b) *Physical/chemical sterilization process indicator* -- (1) *Identification*. A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device.

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

#### **Sec. 880.2900 Clinical color change thermometer.**

(a) *Identification*. A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature. The device records body temperature by use of heat sensitive chemicals which are sealed at the end of a plastic or metal strip. Body heat causes a stable color change in the heat sensitive chemicals.

(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 880.9.

#### **Sec. 880.2910 Clinical electronic thermometer.**

(a) *Identification*. A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without

a disposable cover.

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

**Sec. 880.2920 Clinical mercury thermometer.**

(a) *Identification*. A clinical mercury thermometer is a device used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury.

(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 880.9.

#### **Sec. 880.2930 Apgar timer.**

(a) *Identification.* The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.

(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 880.9. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of 820.180 of this chapter, with respect to general requirements concerning records, and 820.198 of this chapter, with respect to complaint files.

### **Subparts D-E [Reserved]**

## **Subpart F--General Hospital and Personal Use Therapeutic Devices**

#### **Sec. 880.5025 I.V. container.**

(a) *Identification.* An I.V. container is a container made of plastic or glass used to hold a fluid mixture to be administered to a patient through an intravascular administration set.

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

#### **Sec. 880.5045 Medical recirculating air cleaner.**

(a) *Identification.* A medical recirculating air cleaner is a device used to remove particles from the air for medical purposes. The device

may function by electrostatic precipitation or filtration.

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

#### **Sec. 880.5075 Elastic bandage.**

(a) *Identification*. An elastic bandage is a device consisting of either a long flat strip or a tube of elasticized material that is used to support and compress a part of a patient's body.

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5090 Liquid bandage.**

(a) *Identification*. A liquid bandage is a sterile device that is a liquid, semiliquid, or powder and liquid combination used to cover an opening in the skin or as a dressing for burns. The device is also used as a topical skin protectant.

(b) *Classification*. Class I (general controls). When used only as a skin protectant, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 880.9.

#### **Sec. 880.5100 AC-powered adjustable hospital bed.**



(a) *Identification*. An AC-powered adjustable hospital bed is a device intended for medical purposes that consists of a bed with a built-in electric motor and remote controls that can be operated by the patient to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.

(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 880.9.

#### **Sec. 880.5110 Hydraulic adjustable hospital bed.**

(a) *Identification*. A hydraulic adjustable hospital bed is a device intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.

(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 880.9.

#### **Sec. 880.5120 Manual adjustable hospital bed.**

(a) *Identification*. A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5130 Infant radiant warmer.**

(a) *Identification.* The infant radiant warmer is a device consisting of an infrared heating element intended to be placed over an infant to maintain the infant's body temperature by means of radiant heat. The device may also contain a temperature monitoring sensor, a heat output control mechanism, and an alarm system (infant temperature, manual mode if present, and failure alarms) to alert operators of a temperature condition over or under the set temperature, manual mode time limits, and device component failure, respectively. The device may be placed over a pediatric hospital bed or it may be built into the bed as a complete unit.

(b) *Classification.* Class II (Special Controls):

(1) The Association for the Advancement of Medical Instrumentation (AAMI) Voluntary Standard for the Infant Radiant Warmer;

(2) A prescription statement in accordance with 801.109 of this chapter (restricted to use by or upon the order of qualified practitioners as determined by the States); and

(3) Labeling for use only in health care facilities and only by persons with specific training and experience in the use of the device.

#### **Sec. 880.5140 Pediatric hospital bed.**

(a) *Identification.* A pediatric hospital bed is a device intended for medical purposes that consists of a bed or crib designed for the use of a pediatric patient, with fixed end rails and movable and latchable side rails. The contour of the bed surface may be adjustable.

(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 880.9.

#### **Sec. 880.5150 Nonpowered flotation therapy mattress.**

(a) *Identification.* A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials that have the functionally equivalent effect of supporting a patient and avoiding excess pressure on local body areas. The device is intended to treat or prevent decubitus ulcers (bed sores).

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5160 Therapeutic medical binder.**

(a) *Identification.* A therapeutic medical binder is a device, usually made of cloth, that is intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place. This generic type of device includes the abdominal binder, breast binder, and perineal binder.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5180 Burn sheet.**

(a) *Identification.* A burn sheet is a device made of a porous material that is wrapped around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants.

(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 880.9.

#### **Sec. 880.5200 Intravascular catheter.**

(a) *Identification.* An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.

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

#### **Sec. 880.5210 Intravascular catheter securement device.**

(a) *Identification.* An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin.

(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 880.9.

#### **Sec. 880.5240 Medical adhesive tape and adhesive bandage.**

(a) *Identification.* A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant. The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin.

(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 880.9.

#### **Sec. 880.5270 Neonatal eye pad.**

(a) *Identification.* A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it is 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 of this chapter, with respect to general requirements concerning records, and 820.198 of this chapter, with respect to complaint files.

#### **Sec. 880.5300 Medical absorbent fiber.**

(a) *Identification.* A medical absorbent fiber is a device intended for medical purposes that is made from cotton or synthetic fiber in the

shape of a ball or a pad and that is used for applying medication to, or absorbing small amounts of body fluids from, a patient's body surface. Absorbent fibers intended solely for cosmetic purposes are not included in this generic device category.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5400 Neonatal incubator.**

(a) *Identification*. A neonatal incubator is a device consisting of a rigid boxlike enclosure in which an infant may be kept in a controlled environment for medical care. The device may include an AC-powered heater, a fan to circulate the warmed air, a container for water to add humidity, a control valve through which oxygen may be added, and access ports for nursing care.

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

#### **Sec. 880.5410 Neonatal transport incubator.**

(a) *Identification*. A neonatal transport incubator is a device consisting of a portable rigid boxlike enclosure with insulated walls in which an infant may be kept in a controlled environment while being transported for medical care. The device may include straps to secure the infant, a battery-operated heater, an AC-powered battery charger,



a fan to circulate the warmed air, a container for water to add humidity, and provision for a portable oxygen bottle.

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

#### **Sec. 880.5420 Pressure infusor for an I.V. bag.**

(a) *Identification.* A pressure infusor for an I.V. bag is a device consisting of an inflatable cuff which is placed around an I.V. bag. When the device is inflated, it increases the pressure on the I.V. bag to assist the infusion of the fluid.

(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 880.9.

#### **Sec. 880.5430 Nonelectrically powered fluid injector.**

(a) *Identification.* A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations.

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

#### **Sec. 880.5440 Intravascular administration set.**

(a) *Identification.* An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

(b) *Classification.* Class II (special controls). The special control

for pharmacy compounding systems within this classification is the FDA guidance document entitled "Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers." Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in 880.9.

**Sec. 880.5445 Intravascular administration set, automated air removal system.**

(a) *Identification.* An intravascular administration set, automated air removal system, is a prescription device used to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid. The device may include an air identification mechanism, software, an air removal mechanism, tubing, apparatus to collect removed air, and safety control mechanisms to address hazardous situations.

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

(1) Provide an argument demonstrating that all reasonably foreseeable hazards have been adequately addressed with respect to the persons for whose use the device is represented or intended and the conditions of use for the device, which includes the following:

(i) Description of the device indications for use, design, and technology, use environments, and users in sufficient detail to determine that the device complies with all special controls.

(ii) Demonstrate that controls are implemented to address device system hazards and their causes.

(iii) Include a justification supporting the acceptability criteria for each hazard control.

(iv) A traceability analysis demonstrating that all credible hazards

have at least one corresponding control and that all controls have been verified and validated in the final device design.

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

(3) The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of fluid path contacting components and the shelf life of these components.

(5) The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC).

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

(i) Device system and component reliability testing must be conducted.

(ii) Fluid ingress protection testing must be conducted.

(iii) Testing of safety controls must be performed to demonstrate adequate mitigation of hazardous situations, including sensor failure, flow control failure, improper device position, device malfunction, infusion delivery error, and release of air to the patient.

(7) A human factors validation study must demonstrate that use hazards are adequately addressed.

(8) The labeling must include the following:

(i) The device's air identification and removal response time.

(ii) The device's minimum air volume identification sensitivity.

(iii) The minimum and maximum flow rates at which the device is capable of reliably detecting and removing air.

(iv) Quantification of any fluid loss during device air removal operations as a function of flow rate.

#### **Sec. 880.5450 Patient care reverse isolation chamber.**

(a) *Identification.* A patient care reverse isolation chamber is a device consisting of a roomlike enclosure designed to prevent the entry of harmful airborne material. This device protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality. The device includes fans and air filters which maintain an atmosphere of clean air at a pressure greater than the air pressure outside the enclosure.

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

#### **Sec. 880.5475 Jet lavage.**

(a) *Identification.* A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid. The device consists of the pulsing head, tubing to connect to a container of sterile fluid, and a means of propelling the fluid through the tubing, such as an electric roller pump.

(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 880.9.

#### **Sec. 880.5500 AC-powered patient lift.**

(a) *Identification.* An AC-powered lift is an electrically powered device either fixed or mobile, used to lift and transport patients in

the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and slings to support the patient.

(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 880.9.

#### **Sec. 880.5510 Non-AC-powered patient lift.**

(a) *Identification.* A non-AC-powered patient lift is a hydraulic, battery, or mechanically powered device, either fixed or mobile, used to lift and transport a patient in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and a sling to support the 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 880.9.

#### **Sec. 880.5550 Alternating pressure air flotation mattress.**

(a) *Identification.* An alternating pressure air flotation mattress is a device intended for medical purposes that consists of a mattress with multiple air cells that can be filled and emptied in an alternating pattern by an associated control unit to provide regular, frequent, and automatic changes in the distribution of body pressure. The device is used to prevent and treat decubitus ulcers (bed sores).

(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 880.9.

#### **Sec. 880.5560 Temperature regulated water mattress.**

(a) *Identification.* A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control

may be manual or automatic.

(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 880.9.

#### **Sec. 880.5570 Hypodermic single lumen needle.**

(a) *Identification*. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

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

#### **Sec. 880.5580 Acupuncture needle.**

(a) *Identification*. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification*. Class II (special controls). Acupuncture needles must comply with the following special controls:

- (1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,
- (2) Device material biocompatibility, and
- (3) Device sterility.





#### **Sec. 880.5630 Nipple shield.**

(a) *Identification.* A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(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 880.9.

#### **Sec. 880.5640 Lamb feeding nipple.**

(a) *Identification.* A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5680 Pediatric position holder.**

(a) *Identification.* A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an intravascular injection is administered.

(b) *Classification.* Class I (general controls). The device is exempt

from the good manufacturing practice regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

**Sec. 880.5700 Neonatal phototherapy unit.**

(a) *Identification.* A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy. This generic type of device may include supports for the patient and equipment and component parts.

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

**Sec. 880.5725 Infusion pump.**

(a) *Identification.* An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.

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

**Sec. 880.5740 Suction snakebite kit.**

(a) *Identification*. A suction snakebite kit is a device consisting of a knife, suction device, and tourniquet used for first-aid treatment of snakebites by removing venom from the wound.

(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 880.9.

#### **Sec. 880.5760 Chemical cold pack snakebite kit.**

(a) *Identification*. A chemical cold pack snakebite kit is a device consisting of a chemical cold pack and tourniquet used for first-aid treatment of snakebites.

(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 chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976. Any other chemical cold pack snakebite kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

#### **Sec. 880.5780 Medical support stocking.**

(a) *Medical support stocking to prevent the pooling of blood in the legs -- (1) Identification*. A medical support stocking to prevent the pooling of blood in the legs is a device that is constructed of elastic

material and designed to apply controlled pressure to the leg and that is intended for use in the prevention of pooling of blood in the leg.

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

(b) *Medical support stocking for general medical purposes* -- (1)

*Identification*. A medical support stocking for general medical purposes is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for medical purposes other than the prevention of pooling of blood in the leg.

(2) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5820 Therapeutic scrotal support.**

(a) *Identification*. A therapeutic scrotal support is a device intended for medical purposes that consist of a pouch attached to an elastic waistband and that is used to support the scrotum (the sac that contains the testicles).

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.5860 Piston syringe.**

(a) *Identification.* A piston syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.

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

#### **Sec. 880.5950 Umbilical occlusion device.**

(a) *Identification.* An umbilical occlusion device is a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.

(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 880.9.

#### **Sec. 880.5960 Lice removal kit.**

(a) *Identification.* The lice removal kit is a comb or comb-like device intended to remove and/or kill lice and nits from head and body hair. It may or may not be battery operated.

(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 880.9.

**Sec. 880.5965 Subcutaneous, implanted, intravascular infusion port and catheter.**

(a) *Identification.* A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body with a resealable septum and outlet made of metal, plastic, or combination of these materials and a long-term intravascular catheter is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.

(b) *Classification.* Class II (special controls) Guidance Document: "Guidance on 510(k) Submissions for Implanted Infusion Ports," FDA October 1990.

**Sec. 880.5970 Percutaneous, implanted, long-term intravascular catheter.**

(a) *Identification.* A percutaneous, implanted, long-term intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings, such as luer hubs, and accessories that facilitate the placement of the device. The device allows for repeated access to the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature. The device may be constructed of metal, rubber, plastic, composite materials, or any combination of these materials and may be of single

or multiple lumen design.

(b) *Classification*. Class II (special controls) Guidance Document: "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters."

## Subpart G--General Hospital and Personal Use Miscellaneous Devices

### Sec. 880.6025 Absorbent tipped applicator.

(a) *Identification*. An absorbent tipped applicator is a device intended for medical purposes that consists of an absorbent swab on a wooden, paper, or plastic stick. The device is used to apply medications to, or to take specimens from, a 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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

### Sec. 880.6050 Ice bag.

(a) *Identification*. An ice bag is a device intended for medical purposes that is in the form of a container intended to be filled with ice that is used to apply dry cold therapy to an area of the body. The device may include a holder that keeps the bag in place against an external



area of the 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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6060 Medical disposable bedding.**

(a) *Identification*. Medical disposable bedding is a device intended for medical purposes to be used by one patient for a period of time and then discarded. This generic type of device may include disposable bedsheets, bedpads, pillows and pillowcases, blankets, emergency rescue blankets, or waterproof sheets.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6070 Bed board.**

(a) *Identification*. A bed board is a device intended for medical purposes

that consists of a stiff board used to increase the firmness of a bed.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6080 Cardiopulmonary resuscitation board.**

(a) *Identification*. A cardiopulmonary resuscitation board is a device consisting of a rigid board which is placed under a patient to act as a support during cardiopulmonary resuscitation.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6085 Hot/cold water bottle.**

(a) *Identification*. A hot/cold water bottle is a device intended for medical purposes that is in the form of a container intended to be filled with hot or cold water to apply heat or cold to an area of the body.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

**Sec. 880.6100 Ethylene oxide gas aerator cabinet.**

(a) *Identification.* An ethylene oxide gas aerator cabinet is a device that is intended for use by a health care provider and consists of a cabinet with a ventilation system designed to circulate and exchange the air in the cabinet to shorten the time required to remove residual ethylene oxide (ETO) from wrapped medical devices that have undergone ETO sterilization. The device may include a heater to warm the circulating air.

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

#### **Sec. 880.6140 Medical chair and table.**

(a) *Identification.* A medical chair or table is a device intended for medical purposes that consists of a chair or table without wheels and not electrically powered which, by reason of special shape or attachments, such as food trays or headrests, or special features such as a built-in raising and lowering mechanism or removable arms, is intended for use of blood donors, geriatric patients, or patients undergoing 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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6150 Ultrasonic cleaner for medical instruments.**

(a) *Identification.* An ultrasonic cleaner for medical instruments is a device intended for cleaning medical instruments by the emission of high frequency soundwaves.

(b) *Classification.* Class I. The device, including any solutions intended for use with the device for cleaning and sanitizing the instruments, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9.

#### **Sec. 880.6175 [Reserved]**

#### **Sec. 880.6185 Cast cover.**

(a) *Identification.* A cast cover is a device intended for medical purposes that is made of waterproof material and placed over a cast to protect it from getting wet during a shower or a bath.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6190 Mattress cover for medical purposes.**

(a) *Identification.* A mattress cover for medical purposes is a device intended for medical purposes that is used to protect a mattress. It may be electrically conductive or contain a germicide.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6200 Ring cutter.**

(a) *Identification.* A ring cutter is a device intended for medical

purposes that is used to cut a ring on a patient's finger so that the ring can be removed. The device incorporates a guard to prevent injury to the patient's finger.

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6230 Tongue depressor.**

(a) *Identification*. A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6250 Patient examination glove.**

(a) *Identification*. A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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

**Sec. 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.**

(a) *Identification.* A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

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

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies." See 880.1(e) for information on obtaining a copy of this guidance document.

**Sec. 880.6265 Examination gown.**

(a) *Identification.* An examination gown is a device intended for medical purposes that is made of cloth, paper, or other material that is draped over or worn by a patient as a body covering during a medical 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 880.9. If the device



is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6280 Medical insole.**

(a) *Identification.* A medical insole is a device intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.

(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 880.9.

#### **Sec. 880.6300 Implantable radiofrequency transponder system for patient identification and health information.**

(a) *Identification.* An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information." See 880.1(e) for the

availability of this guidance document. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 880.9.

#### **Sec. 880.6305 Ingestible event marker.**

(a) *Identification.* An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

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

- (1) The device must be demonstrated to be biocompatible and non-toxic;
- (2) Nonclinical, animal, and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;
- (3) Appropriate analysis and nonclinical testing must validate electromagnetic compatibility performance, wireless performance, and electrical safety; and
- (4) Labeling must include a detailed summary of the nonclinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

#### **Sec. 880.6310 Medical device data system.**

(a) *Identification.* (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

- (i) The electronic transfer of medical device data;

- (ii) The electronic storage of medical device data;
  - (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
  - (iv) The electronic display of medical device data.
- (2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.
- (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 880.9.

#### **Sec. 880.6315 Remote Medication Management System.**

- (a) *Identification*. A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional. The system is intended for use as an aid to health care professionals in managing therapeutic regimens for patients in the home or clinic.
- (b) *Classification*. Class II (special controls). The special control is: The FDA guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System." See 880.1(e) for availability of this guidance document.

#### **Sec. 880.6320 AC-powered medical examination light.**

(a) *Identification.* An AC-powered medical examination light is an AC-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical 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 880.9.

#### **Sec. 880.6350 Battery-powered medical examination light.**

(a) *Identification.* A battery-powered medical examination light is a battery-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical 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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6375 Patient lubricant.**

(a) *Identification.* A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry

of a diagnostic or therapeutic device.

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

#### **Sec. 880.6430 Liquid medication dispenser.**

(a) *Identification.* A Liquid medication dispenser is a device intended for medical purposes that is used to issue a measured amount of liquid medication.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6450 Skin pressure protectors.**

(a) *Identification.* A skin pressure protector is a device intended for medical purposes that is used to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores).

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6500 Medical ultraviolet air purifier.**

(a) *Identification.* A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the

air by exposure to ultraviolet radiation.

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

**Sec. 880.6600 Ultraviolet (UV) radiation chamber disinfection device.**

(a) *Identification*. An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment.

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

(1) Performance testing must demonstrate the following:

(i) The chamber's ability to control the UV radiation dose during operation.

(ii) The chamber's disinfection performance through microbial challenge testing.

(iii) Evidence that the equipment intended to be processed is UV compatible.

(iv) Validation of the cleaning and disinfection procedures.

(v) The ability of the device to continue to perform to all specification after cleaning and disinfection.

(vi) Whether the device generates ozone (if so, 21 CFR 801.415, Maximum acceptable level of ozone, applies).

(2) Appropriate software verification, validation, and hazard analysis



must be performed.

(3) Appropriate analysis and/or testing must validate electrical safety, mechanical safety, and electromagnetic compatibility of the device in its intended use environment.

(4) The labeling must include:

(i) UV hazard warning labels.

(ii) Explanation of all displays and/or labeling on user interface.

(iii) Explanation of device safety interlocks.

(iv) Explanation of all disinfection cycle signals, cautions and warnings.

(v) Device operating procedures.

(vi) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.

(vii) Procedures to follow in case of UV lamp malfunction or failure.

(viii) Procedures for disposing of mercury-containing UV lamps, if applicable.

(ix) Identification of specific equipment that is compatible with the UV radiation dose generated by the device and that can safely undergo UV radiation low-level disinfection in the chamber device.

(x) Description of the required preparation of equipment for disinfection in the UV radiation chamber device.

(xi) Identification of the specific microbes used in successful performance testing of the device.

(xii) Validated instructions for cleaning and disinfection of the device.

**Sec. 880.6710 Medical ultraviolet water purifier.**

(a) *Identification.* A medical ultraviolet water purifier is a device intended for medical purposes that is used to destroy bacteria in water by exposure to ultraviolet radiation.

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

**Sec. 880.6730 Body waste receptacle.**

(a) *Identification.* A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed 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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

**Sec. 880.6740 Vacuum-powered body fluid suction apparatus.**

(a) *Identification.* A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction

catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).

(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 880.9.

**Sec. 880.6760 Protective restraint.**

(a) *Identification.* A protective restraint is a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

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

**Sec. 880.6775 Powered patient transfer device.**

(a) *Identification.* A powered patient transfer device is a device consisting of a wheeled stretcher and a powered mechanism that has a broad, flexible band stretched over long rollers that can advance itself under a patient and transfer the patient with minimal disturbance in a horizontal position to the stretcher.

(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 880.9.

**Sec. 880.6785 Manual patient transfer device.**

(a) *Identification.* A manual patient transfer device is a device consisting of a wheeled stretcher and a mechanism on which a patient can be placed so that the patient can be transferred with minimal disturbance in a horizontal position to the stretcher.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6800 Washers for body waste receptacles.**

(a) *Identification.* A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan. The device consists of a wall-mounted plumbing fixture with a door through which a body waste receptacle is inserted. When the door is closed the body waste receptacle is cleaned by hot water, steam, or germicide.

(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 880.9. The device also is 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6820 Medical disposable scissors.**

(a) *Identification.* Medical disposable scissors are disposable type general cutting devices intended for medical purposes. This generic type of device does not include surgical scissors.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9.

**Sec. 880.6850 Sterilization wrap.**

(a) *Identification.* A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

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

**Sec. 880.6860 Ethylene oxide gas sterilizer.**

(a) *Identification.* An ethylene gas sterilizer is a nonportable device intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical products.

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

**Sec. 880.6870 Dry-heat sterilizer.**

(a) *Identification.* A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical products by means of dry heat.

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

#### **Sec. 880.6880 Steam sterilizer.**

#### **Sec. 880.6885 Liquid chemical sterilants/high level disinfectants.**

(a) *Identification.* A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.

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

(a) *Identification.* A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or body spaces during use. Semicritical devices make contact during use with mucous membranes or nonintact skin.

(b) *Classification.* Class II (special controls). Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants, and user information and training.

#### **Sec. 880.6890 General purpose disinfectants.**

(a) *Identification*. A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices make only topical contact with intact skin.

(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 880.9.

#### **Sec. 880.6900 Hand-carried stretcher.**

(a) *Identification*. A hand-carried stretcher is a device consisting of a lightweight frame, or of two poles with a cloth or metal platform, on which a patient can be carried.

(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 880.9. 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6910 Wheeled stretcher.**

(a) *Identification*. A wheeled stretcher is a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position. The device may have side rails, supports for fluid infusion equipment, and patient securement straps.



The frame may be fixed or collapsible for use in an ambulance.

(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 880.9.

#### **Sec. 880.6920 Syringe needle introducer.**

(a) *Identification*. A syringe needle introducer is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface.

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

#### **Sec. 880.6960 Irrigating syringe.**

(a) *Identification.* An irrigating syringe is a device intended for medical purposes that consists of a bulb or a piston syringe with an integral or a detachable tube. The device is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6970 Liquid crystal vein locator.**

(a) *Identification.* A liquid crystal vein locator is a device used to indicate the location of a vein by revealing variations in the surface temperature of the skin by displaying the color changes of heat sensitive liquid crystals (cholesteric esters).

(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 880.9.

#### **Sec. 880.6980 Vein stabilizer.**

(a) *Identification.* A vein stabilizer is a device consisting of a flat piece of plastic with two noninvasive prongs. The device is placed on the skin so that the prongs are on either side of a vein and hold it

stable while a hypodermic needle is inserted into the vein.

(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 880.9. If the device is not labeled or otherwise represented as sterile, it 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, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

#### **Sec. 880.6990 Infusion stand.**

(a) *Identification*. The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(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 880.9.

#### **Sec. 880.6991 Medical washer.**

(a) *Identification*. A medical washer is a device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors." The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject

to 880.9.

#### **Sec. 880.6992 Medical washer-disinfector.**

(a) *Identification.* A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors."

(1) Medical washer-disinfectors that are intended to clean, high level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(2) Medical washer-disinfectors that are intended to clean, low or intermediate level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 880.9.

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