

Food and Drug Administration, HHS

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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).

§ 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38805, July 25, 2001]

§ 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.

[63 FR 59718, Nov. 5, 1998]

§ 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.

[65 FR 37043, June 13, 2000]

§ 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."

[65 FR 37043, June 13, 2000]

Subpart G—General Hospital and Personal Use Miscellaneous Devices

§ 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,

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

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 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 water-proof 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

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concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38805, July 25, 2001]

§ 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 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.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 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.