

### 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. If the device is not labeled or otherwise represented as sterile, it also is exempt from the good manufacturing practice 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.

#### § 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. If the device is not labeled or otherwise represented as sterile, it also is exempt from the good manufacturing practice 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.

#### § 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. The device is exempt from the premarket notification procedures in subpart E of part 807

of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations 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 59 FR 63011, Dec. 7, 1994]

#### § 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. The device also is exempt from the good manufacturing practice 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.

#### § 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. The device also is exempt from the good manufacturing practice 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.

#### § 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. The device also is exempt from the good manufacturing practice 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.

**§ 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).

**§ 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. The device also is exempt from the good manufacturing practice 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.

**§ 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 proce-

dures in subpart E of part 807 of this chapter.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 59 FR 63011, Dec. 7, 1994]

**§ 880.6175 [Reserved]**

**§ 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 premarket notification procedures in subpart 807. If the device is not labeled or otherwise represented as sterile it is also exempt from the good manufacturing practice 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.

**§ 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations 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 59 FR 63011, Dec. 7, 1994]

**§ 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