

§ 880.6800

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.

§ 880.6800 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. 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.

§ 880.6820 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 premarket notification procedures in subpart E of part 807.

§ 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).

§ 880.6860 Ethylene oxide gas sterilizer.

(a) *Identification.* An ethylene gas sterilizer is a nonportable device intended for use by a health care pro-

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vider that uses ethylene oxide (ETO) to sterilize medical products.

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

§ 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).

§ 880.6880 Steam sterilizer.

(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).

§ 880.6885 Liquid chemical sterilants/high level disinfectants.

(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.

[65 FR 36325, June 8, 2000]

§ 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