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.

[66 FR 38806, July 25, 2001]

§ 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.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 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).

[61 FR 8439, Mar. 4, 1996, as amended at 66 FR 46952, Sept. 10, 2001]

§ 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.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 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.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 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.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 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.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 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 provider 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 subpart E of part 807 of this chapter subject to the limitations in § 880.9.

[65 FR 36326, June 8, 2000]

§ 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,