Food and Drug Administration, HHS

§ 880.6900

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]

§ 880.6800 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,