Food and Drug Administration, HHS

§880.2930  **Apgar timer.**

(a) **Identification.** The Apgar timer is a device intended to alert a health care provider to take the Apgar score 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. 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.

[63 FR 59718, Nov. 5, 1998]

Subparts D–E [Reserved]

Subpart F—General Hospital and Personal Use Therapeutic Devices

§880.5025  **I.V. container.**

(a) **Identification.** An I.V. container is a container made of plastic or glass used to hold a fluid mixture to be administered to a patient through an intravascular administration set.

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

§880.5045  **Medical recirculating air cleaner.**

(a) **Identification.** A medical recirculating air cleaner is a device used to remove particles from the air for medical purposes. The device may function by electrostatic precipitation or filtration.

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

§880.5075  **Elastic bandage.**

(a) **Identification.** An elastic bandage is a device consisting of either a long flat strip or a tube of elasticized material that is used to support and compress a part of a patient’s body.

(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.


§880.5090  **Liquid bandage.**

(a) **Identification.** A liquid bandage is a sterile device that is a liquid, semiliquid, or powder and liquid combination used to cover an opening in the skin or as a dressing for burns. The device is also used as a topical skin protectant.

(b) **Classification.** Class I (general controls). When used only as a skin protectant, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §880.9.


§880.5100  **AC-powered adjustable hospital bed.**

(a) **Identification.** An AC-powered adjustable hospital bed is a device intended for medical purposes that consists of a bed with a built-in electric motor and remote controls that can be operated by the patient to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.

(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.


§880.5110  **Hydraulic adjustable hospital bed.**

(a) **Identification.** A hydraulic adjustable hospital bed is a device intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed.