§ 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 § 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 respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 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. The device includes movable and latchable side rails.

(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.

§ 880.5120 Manual adjustable hospital bed.

(a) Identification. A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.

(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 respect to general requirements concerning records, and § 820.198, with respect to complaint files.