§ 880.2930

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

§ 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 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.
[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 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.

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