causes a stable color change in the heat sensitive chemicals.

(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.


§ 880.2910 Clinical electronic thermometer.

(a) Identification. A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

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

§ 880.2920 Clinical mercury thermometer.

(a) Identification. A clinical mercury thermometer is a device used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury.

(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.


§ 880.2930 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]

§ 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

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