§ 880.2800 Sterilization process indicator.

(a) Biological sterilization process indicator—(1) Identification. A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.

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

(b) Physical/chemical sterilization process indicator—(1) Identification. A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device.

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

§ 880.2900 Clinical color change thermometer.

(a) Identification. A clinical color change thermometer is a disposable device used to measure a patient’s oral, rectal, or axillary (armpit) body temperature. The device records body temperature by use of heat sensitive chemicals which are sealed at the end of a plastic or metal strip. Body heat 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 is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

[63 FR 59718, Nov. 5, 1998]