

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

**§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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996]

**§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 (performance standards).

**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 premarket notification procedures in subpart E of part 807. If the device is not