

Food and Drug Administration, HHS

§ 880.5725

(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]

§ 880.5570 Hypodermic single lumen needle.

(a) *Identification*. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

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

§ 880.5580 Acupuncture needle.

(a) *Identification*. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification*. Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

§ 880.5630 Nipple shield.

(a) *Identification*. A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(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 59 FR 63011, Dec. 7, 1994]

§ 880.5640 Lamb feeding nipple.

(a) *Identification*. A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it also is exempt from the good manufacturing practice regulation in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 880.5680 Pediatric position holder.

(a) *Identification*. A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an intravascular injection is administered.

(b) *Classification*. Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 880.5700 Neonatal phototherapy unit.

(a) *Identification*. A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy. This generic type of device may include supports for the patient and equipment and component parts.

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

§ 880.5725 Infusion pump.

(a) *Identification*. An infusion pump is a device used in a health care facility