

(2) *Classification*. Class I. 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.

[45 FR 69682, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38805, July 25, 2001]

§ 880.5820 Therapeutic scrotal support.

(a) *Identification*. A therapeutic scrotal support is a device intended for medical purposes that consist of a pouch attached to an elastic waistband and that is used to support the scrotum (the sac that contains the testicles).

(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.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38805, July 25, 2001]

§ 880.5860 Piston syringe.

(a) *Identification*. A piston syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.

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

§ 880.5950 Umbilical occlusion device.

(a) *Identification*. An umbilical occlusion device is a clip, tie, tape, or other article used to close the blood vessels

in the umbilical cord 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.

[45 FR 69682, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38805, July 25, 2001]

§ 880.5960 Lice removal kit.

(a) *Identification*. The lice removal kit is a comb or comb-like device intended to remove and/or kill lice and nits from head and body hair. It may or may not be battery operated.

(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.

[63 FR 59718, Nov. 5, 1998]

§ 880.5965 Subcutaneous, implanted, intravascular infusion port and catheter.

(a) *Identification*. A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body with a resealable septum and outlet made of metal, plastic, or combination of these materials and a long-term intravascular catheter is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.

(b) *Classification*. Class II (special controls) Guidance Document: "Guidance on 510(k) Submissions for Implanted Infusion Ports," FDA October 1990.

[65 FR 37043, June 13, 2000]