

§ 888.4150

medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) *Classification*. Class II.

Subpart E—Surgical Devices

§ 888.4150 Calipers for clinical use.

(a) *Identification*. A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(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 § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.4200 Cement dispenser.

(a) *Identification*. A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (§ 888.3027) into surgical sites.

(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 § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52953, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§ 888.4210 Cement mixer for clinical use.

(a) *Identification*. A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement (§ 888.3027).

(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 § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52953, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

21 CFR Ch. I (4–1–10 Edition)

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification*. A cement monomer vapor evacuator is a device intended for use during surgery to contain or remove undesirable fumes, such as monomer vapor from bone cement (§ 888.3027).

(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 § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 66 FR 38815, July 25, 2001]

§ 888.4230 Cement ventilation tube.

(a) *Identification*. A cement ventilation tube is a tube-like device usually made of plastic intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement (§ 888.3027).

(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 § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§ 888.4300 Depth gauge for clinical use.

(a) *Identification*. A depth gauge for clinical use is a measuring device intended for various medical purposes, such as to determine the proper length of screws for fastening the ends of a fractured bone.

(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 § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.4540 Orthopedic manual surgical instrument.

(a) *Identification*. An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl,