Food and Drug Administration, HHS

§ 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.


§ 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.


§ 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.


§ 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,