Food and Drug Administration, HHS

§ 888.5940 Cast component.

(a) Identification. A cast component is a device intended for medical purposes, subject to the limitations in § 888.9.


§ 888.5850 Nonpowered orthopedic traction apparatus and accessories.

(a) Identification. A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

(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.


§ 888.5890 Noninvasive traction component.

(a) Identification. A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient’s body.

(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.


§ 888.5840 Protractor for clinical use.

(a) Identification. A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on x-rays or in surgery.

(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.


§ 888.4800 Template for clinical use.

(a) Identification. A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

(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.


§ 888.4820 Sonic surgical instrument and accessories/attachments.

(a) Identification. A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

(b) Classification. Class II.