

§ 888.5850

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

§ 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. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the current good manufacturing practice regulations in part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988]

§ 888.5940 Cast component.

(a) *Identification*. A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufac-

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turing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

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

§ 888.5960 Cast removal instrument.

(a) *Identification*. A cast removal instrument is an AC-powered, hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48443, Nov. 20, 1990, as amended at 61 FR 1125, Jan. 16, 1996]

§ 888.5980 Manual cast application and removal instrument.

(a) *Identification*. A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988]

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

Sec.

890.1 Scope.

890.3 Effective dates of requirement for premarket approval.

890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).