

other ultrasound and muscle stimulator described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 64 FR 18331, Apr. 14, 1999]

§ 890.5880 Multi-function physical therapy table.

(a) *Identification.* A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.

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

§ 890.5900 Power traction equipment.

(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

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

§ 890.5925 Traction accessory.

(a) *Identification.* A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.

(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 § 890.9. 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, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5940 Chilling unit.

(a) *Identification.* A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.

(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 § 890.9

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5950 Powered heating unit.

(a) *Identification.* A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5975 Therapeutic vibrator.

(a) *Identification.* A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

PART 892—RADIOLOGY DEVICES

Subpart A—General Provisions

Sec.

892.1 Scope.

892.3 Effective dates of requirement for premarket approval.

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