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.


§ 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.


§ 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.


§ 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.


§ 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.


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).