§ 890.5740 Powered heating pad.

(a) Identification. A powered heating pad is an electrical device intended for medical purposes to provide dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to paragraph (b) of this section.


§ 890.5765 Pressure-applying device.

(a) Identification. A pressure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist’s hands, presses on the back of a prone patient.

(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.


§ 890.5850 Powered muscle stimulator.

(a) Identification. A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

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

§ 890.5860 Ultrasound and muscle stimulator.

(a) Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions—(1) Identification. An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. The device also passes electrical currents through the body area to stimulate or relax muscles.

(2) Classification. Class II (performance standards).

(b) Ultrasound and muscle stimulator for all other uses—(1) Identification. An ultrasound and muscle stimulator for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and applies to the body electrical currents for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles as described in paragraph (a) of this section.

(2) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any

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§ 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.
892.2 Effective dates of requirement for premarket approval.
892.3 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).