Food and Drug Administration, HHS

§ 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 and that is intended 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 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...