

an electrode from a patient to a diagnostic machine.

(b) *Classification*. Class II (special controls). The special controls consist of:

(1) The performance standard under part 898 of this chapter, and

(2) The guidance document entitled "Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables." This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 65 FR 19319, Apr. 11, 2000]

§ 890.1225 Chronaximeter.

(a) *Identification*. A chronaximeter is a device intended for medical purposes to measure neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.

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

§ 890.1375 Diagnostic electromyograph.

(a) *Identification*. A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.

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

§ 890.1385 Diagnostic electromyograph needle electrode.

(a) *Identification*. A diagnostic electromyograph needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medical purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle).

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

§ 890.1450 Powered reflex hammer.

(a) *Identification*. A powered reflex hammer is a motorized device intended for medical purposes to elicit and determine controlled deep tendon reflexes.

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

§ 890.1575 Force-measuring platform.

(a) *Identification*. A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.

(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 38816, July 25, 2001]

§ 890.1600 Intermittent pressure measurement system.

(a) *Identification*. An intermittent pressure measurement system is an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media.

(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 38816, July 25, 2001]

§ 890.1615 Miniature pressure transducer.

(a) *Identification*. A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

§ 890.1850

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 38816, July 25, 2001]

§ 890.1850 Diagnostic muscle stimulator.

(a) *Identification.* A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity. It is intended for medical purposes, such as to diagnose motor nerve or sensory neuromuscular disorders and neuromuscular function.

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

§ 890.1925 Isokinetic testing and evaluation system.

(a) *Identification.* An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

(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 § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59230, Nov. 3, 1998]

Subpart C [Reserved]

Subpart D—Physical Medicine Prosthetic Devices

§ 890.3025 Prosthetic and orthotic accessory.

(a) *Identification.* A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.

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

21 CFR Ch. I (4–1–14 Edition)

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 66 FR 38816, July 25, 2001]

§ 890.3075 Cane.

(a) *Identification.* A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.

(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 66 FR 38816, July 25, 2001]

§ 890.3100 Mechanical chair.

(a) *Identification.* A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.

(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 59 FR 63014, Dec. 7, 1994; 66 FR 38816, July 25, 2001]