

**§ 882.1525**

records, and §820.198 of this chapter, with respect to complaint files.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

**§ 882.1525 Tuning fork.**

(a) *Identification.* A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(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 §882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 66 FR 38807, July 25, 2001]

**§ 882.1540 Galvanic skin response measurement device.**

(a) *Identification.* A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

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

**§ 882.1550 Nerve conduction velocity measurement device.**

(a) *Identification.* A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

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

**§ 882.1560 Skin potential measurement device.**

(a) *Identification.* A skin potential measurement device is a general diagnostic device used to measure skin

**21 CFR Ch. I (4-1-08 Edition)**

voltage by means of surface skin electrodes.

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

**§ 882.1570 Powered direct-contact temperature measurement device.**

(a) *Identification.* A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

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

**§ 882.1610 Alpha monitor.**

(a) *Identification.* An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

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

**§ 882.1620 Intracranial pressure monitoring device.**

(a) *Identification.* An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

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

**§ 882.1700 Percussor.**

(a) *Identification.* A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(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 §882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning

## Food and Drug Administration, HHS

## § 882.1870

records, and § 820.198, with respect to complaint files.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 59 FR 63011, Dec. 7, 1994; 66 FR 38807, July 25, 2001]

### § 882.1750 Pinwheel.

(a) *Identification.* A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(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 § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

### § 882.1790 Ocular plethysmograph.

(a) *Identification.* An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) *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 is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any ocular plethysmograph that was in commercial distribution before May 28, 1976. Any other ocular plethysmograph shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17739, May 11, 1987; 69 FR 34920, June 23, 2004]

### § 882.1825 Rheoencephalograph.

(a) *Identification.* A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be

filed with the Food and Drug Administration on or before December 26, 1996 for any rheoencephalograph that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a rheoencephalograph that was in commercial distribution before May 28, 1976. Any other rheoencephalograph shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

### § 882.1835 Physiological signal amplifier.

(a) *Identification.* A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

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

### § 882.1845 Physiological signal conditioner.

(a) *Identification.* A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.

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

### § 882.1855 Electroencephalogram (EEG) telemetry system.

(a) *Identification.* An electroencephalogram (EEG) telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring EEG signals by means of radio or telephone transmission systems.

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

### § 882.1870 Evoked response electrical stimulator.

(a) *Identification.* An evoked response electrical stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.