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tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

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

[44 FR 51730-51778, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996]

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) *Identification*. An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

(b) *Classification*. Class I (general controls).

§ 882.1430 Electroencephalograph test signal generator.

(a) *Identification*. An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

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

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994]

§ 882.1460 Nystagmograph.

(a) *Identification*. A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

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

§ 882.1480 Neurological endoscope.

(a) *Identification*. A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

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

§ 882.1500 Esthesiometer.

(a) *Identification*. An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or

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other examiner and which is used to determine whether a patient has tactile sensitivity.

(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. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. 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 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]

§ 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

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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 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. The device is exempt from the premarket notification procedures in subpart E of part 807

of this chapter. 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 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]

§ 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 a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17739, May 11, 1987]

§ 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