

§ 882.1330 Depth electrode.

(a) *Identification.* A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

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

§ 882.1340 Nasopharyngeal electrode.

(a) *Identification.* A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

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

§ 882.1350 Needle electrode.

(a) *Identification.* A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

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

§ 882.1400 Electroencephalograph.

(a) *Identification.* An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

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

§ 882.1410 Electroencephalograph electrode/lead tester.

(a) *Identification.* An electroencephalograph electrode/lead 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 (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.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38807, July 25, 2001]

§ 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).

[44 FR 51730-51778, Sept. 4, 1979, as amended at 66 FR 46953, Sept. 10, 2001]

§ 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 (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.

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

§ 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 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

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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

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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