<p>§ 882.1430 Electroencephalograph test signal generator.</p>

(a) Identification. An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.<br />

(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.<br />


§ 882.1460 Nystagmograph.<br />

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

(b) Classification. Class II (performance standards).<br />

§ 882.1480 Neurological endoscope.<br />

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

(b) Classification. Class II (performance standards).<br />

§ 882.1500 Esthesiometer.<br />

(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.<br />

(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 requirements of the quality system regulation 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.<br />


§ 882.1525 Tuning fork.<br />

(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.<br />

(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 requirements of the quality system regulation 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.<br />


§ 882.1540 Galvanic skin response measurement device.<br />

(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.<br />

(b) Classification. Class II (performance standards).<br />

§ 882.1550 Nerve conduction velocity measurement device.<br />

(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.<br />

(b) Classification. Class II (performance standards).<br />

§ 882.1560 Skin potential measurement device.<br />

(a) Identification. A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.<br />

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