

Food and Drug Administration, HHS

§ 882.1950

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.

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

§ 882.1880 Evoked response mechanical stimulator.

(a) *Identification.* An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

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

§ 882.1890 Evoked response photic stimulator.

(a) *Identification.* An evoked response photic stimulator is a device used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.

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

§ 882.1900 Evoked response auditory stimulator.

(a) *Identification.* An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

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

§ 882.1925 Ultrasonic scanner calibration test block.

(a) *Identification.* An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).

(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]

§ 882.1950 Tremor transducer.

(a) *Identification.* A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.

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

Subparts C-D [Reserved]