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.


§ 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).

§ 882.1950 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]