Food and Drug Administration, HHS

§882.1950 Tremor transducer.
(a) Identification. A tremor transducer is a device used to measure the patient by means of skin electrodes for the purpose of measuring the evoked response.

§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.

§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.

§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.

§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).

§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).

§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.

§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.

§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.

(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 in commercial distribution before May 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.


Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.
(a) Identification. A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4060 Ventricular cannula.
(a) Identification. A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.
(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.

§ 882.4100 Ventricular catheter.
(a) Identification. A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.
(b) Classification. Class II (performance standards).

§ 882.4125 Neurosurgical chair.
(a) Identification. A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.
(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.

§ 882.4150 Scalp clip.
(a) Identification. A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.
(b) Classification. Class II (performance standards).

§ 882.4175 Aneurysm clip applicer.
(a) Identification. An aneurysm clip applicer is a device used by the surgeon for holding and applying intracranial aneurysm clips.
(b) Classification. Class II (performance standards).

§ 882.4190 Clip forming/cutting instrument.
(a) Identification. A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 882.4200 Clip removal instrument.
(a) Identification. A clip removal instrument is a device used to remove surgical clips from the patient.
(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.

§ 882.4215 Clip rack.
(a) Identification. A clip rack is a device used to hold or store surgical clips during surgery.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in