§ 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.


§ 882.1935 Near Infrared (NIR) Brain Hematoma Detector.
(a) Identification. A Near Infrared (NIR) Brain Hematoma Detector is a noninvasive device that employs near-infrared spectroscopy that is intended to be used to evaluate suspected brain hematomas.
(b) Classification. Class II (special controls). The special controls for this device are:
(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with §801.109 of this chapter;
(2) The labeling must include specific instructions and the clinical training needed for the safe use of this device;
(3) Appropriate analysis/testing should validate electromagnetic compatibility (EMC), electrical safety, and battery characteristics;
(4) Performance data should validate accuracy and precision and safety features;
(5) Any elements of the device that may contact the patient should be demonstrated to be biocompatible; and,
(6) Appropriate software verification, validation, and hazard analysis should be performed.

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§ 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]

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 I (general controls). The device is exempt from the premarket notification procedures in