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.

(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.