§ 882.1750 Pinwheel.

(a) Identification. A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(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 § 882.9.

§ 882.1790 Ocular plethysmograph.

(a) Identification. An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) Classification. Class III (premarket approval).

(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 September 21, 2004 for any 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.

§ 882.1825 Rheoencephalograph.

(a) Identification. A rheoencephalograph is a device used to estimate a patient’s cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(b) Classification. Class III (premarket approval).

§ 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.

[77 FR 16927, Mar. 23, 2012]

§ 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