§ 882.1240 Echoencephalograph.

(a) Identification. An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

(b) Classification. Class II (performance standards).

§ 882.1300 Depth electrode.

(a) Identification. A depth electrode is an electrode used for temporary stimulation or recording electrical signals at subsurface levels of the brain.

(b) Classification. Class II (performance standards).

§ 882.1340 Nasopharyngeal electrode.

(a) Identification. A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

(b) Classification. Class II (performance standards).

§ 882.1350 Needle electrode.

(a) Identification. A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

(b) Classification. Class II (performance standards).

§ 882.1400 Electroencephalograph.

(a) Identification. An electroencephalograph is a device used to measure and record the electrical activity of the patient’s brain obtained by placing two or more electrodes on the head.

(b) Classification. Class II (performance standards).

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) Identification. An electroencephalogram (EEG) signal spectrum analyzer is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

(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.