Food and Drug Administration, HHS

Subpart B—Neurological Diagnostic Devices

§ 882.1020 Rigidity analyzer.
(a) Identification. A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient’s limb to determine the effectiveness of drugs or other treatments.
(b) Classification. Class II (performance standards).

§ 882.1030 Ataxiagraph.
(a) Identification. An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.
(b) Classification. Class I (general controls).

§ 882.1200 Two-point discriminator.
(a) Identification. A two-point discriminator is a device with points used for testing a patient’s touch discrimination.
(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. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

§ 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).

§ 882.1275 Electroconductive media.
(a) Identification. Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.
(b) Classification. Class II (performance standards).

§ 882.1310 Cortical electrode.
(a) Identification. A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain’s electrical activity.
(b) Classification. Class II (performance standards).

§ 882.1320 Cutaneous electrode.
(a) Identification. A cutaneous electrode is an electrode that is applied directly to a patient’s skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.
(b) Classification. Class II (performance standards).

§ 882.1330 Depth electrode.
(a) Identification. A depth electrode is an electrode used for temporary stimulation of, 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
§ 882.1410 Electroencephalograph electrode/lead tester.

(a) Identification. An electroencephalograph electrode/lead tester 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 II (performance standards).

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) Identification. An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

(b) Classification. Class I (general controls).

§ 882.1430 Electroencephalograph test signal generator.

(a) Identification. An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

(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.

§ 882.1440 Nystagmograph.

(a) Identification. A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

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

§ 882.1480 Neurological endoscope.

(a) Identification. A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

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

§ 882.1500 Esthesiometer.

(a) Identification. An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

(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 §820.198 of this chapter, with respect to complaint files.

§ 882.1525 Tuning fork.

(a) Identification. A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(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. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.