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 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).

§ 882.1410 **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 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.

§ 882.1420 **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).

§ 882.1440 **Neuropsychiatric interpretive electroencephalograph assessment aid.**

(a) **Identification.** The neuropsychiatric interpretive electroencephalograph assessment aid is a prescription device that uses a patient’s electroencephalograph (EEG) to...