Food and Drug Administration, HHS

§ 882.1320

(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.


§ 882.1275 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