Food and Drug Administration, HHS

§ 882.1700  Percussor.

(a) Identification. A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(b) Classification. Class I (general controls). The device is 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.


§ 882.1560  Skin potential measurement device.

(a) Identification. A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

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

§ 882.1570  Powered direct-contact temperature measurement device.

(a) Identification. A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

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

§ 882.1610  Alpha monitor.

(a) Identification. An alpha monitor is a device with electrodes that are placed on a patient’s scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

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

§ 882.1620  Intracranial pressure monitoring device.

(a) Identification. An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

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