Food and Drug Administration, HHS

§ 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 respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 20501, June 12, 1989; 66 FR 38807, July 25, 2001]

§ 882.1540 Galvanic skin response measurement device.

(a) Identification. A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

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

§ 882.1550 Nerve conduction velocity measurement device.

(a) Identification. A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient’s peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

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

§ 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 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...