Food and Drug Administration, HHS § 872.1745

Subpart B—Diagnostic Devices

§ 872.1500 Gingival fluid measurer.

(a) Identification. A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(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 §872.9.

§ 872.1720 Pulp tester.

(a) Identification. A pulp tester is an AC or battery powered device intended to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.

(b) Classification. Class II.

§ 872.1730 Electrode gel for pulp testers.

(a) Identification. An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.

(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 §872.9.

§ 872.1740 Caries detection device.

(a) Identification. The caries detection device is a device intended to show the existence of decay in a patient’s tooth by use of electrical current.

(b) Classification. Class II.

§ 872.1745 Laser fluorescence caries detection device.

(a) Identification. A laser fluorescence caries detection device is a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as...