

§ 874.1500

21 CFR Ch. I (4–1–08 Edition)

§ 874.1500 Gustometer.

(a) *Identification.* A gustometer is a battery-powered device that consists of two electrodes that are intended to be placed on both sides of the tongue at different taste centers and that provides a galvanic stimulus resulting in taste sensation. It is used for assessing the sense of taste.

(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 § 874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations 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.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.1600 Olfactory test device.

(a) *Identification.* An olfactory test device is used to determine whether an olfactory loss is present. The device includes one or more odorants that are presented to the patient's nose to subjectively assess the patient's ability to perceive odors.

(b) *Classification.* Class II (special controls). The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Olfactory Test Device." For the availability of this guidance document, see § 874.1(e). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. When indicated for the screening or diagnosis of diseases or conditions other than the loss of olfactory function, the device is not exempt from premarket notification procedures.

[71 FR 32835, June 7, 2006]

§ 874.1800 Air or water caloric stimulator.

(a) *Identification.* An air or water caloric stimulator is a device that delivers a stream of air or water to the ear canal at controlled rates of flow and

temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semicircular canals produce involuntary eye movements that are measured and recorded by a nystagmograph.

(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 § 874.9.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.1820 Surgical nerve stimulator/locator.

(a) *Identification.* A surgical nerve stimulator/locator is a device that is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.

(b) *Classification.* Class II.

§ 874.1925 Toynbee diagnostic tube.

(a) *Identification.* The toynbee diagnostic tube is a listening device intended to determine the degree of openness of the eustachian tube.

(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 § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 874.3300 Hearing Aid.

(a) *Identification.* A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (§ 874.3320), master hearing aid (§ 874.3330), and tinnitus masker (§ 874.3400).

(b) *Classification.* (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.