

Food and Drug Administration, HHS

§ 874.3320

§ 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.

(2) Class II for the bone-conduction hearing aid.

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

§ 874.3305 Wireless air-conduction hearing aid.

(a) *Identification.* A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electro magnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate wireless technology functions; and

(3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation.

(c) *Premarket notification.* The wireless air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[76 FR 34846, June 15, 2011]

§ 874.3310 Hearing aid calibrator and analysis system.

(a) *Identification.* A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. The device consists of an acoustic complex of known cavity volume, a sound level meter, a microphone, oscillators, frequency counters, microphone amplifiers, a distortion analyzer, a chart recorder, and a hearing aid test box.

(b) *Classification.* Class II.

§ 874.3320 Group hearing aid or group auditory trainer.

(a) *Identification.* A group hearing aid or group auditory trainer is a hearing aid that is intended for use in communicating simultaneously with one or more listeners having hearing impairment. The device is used with an associated transmitter microphone. It may be either monaural or binaural, and it provides coupling to the ear through either earphones or earmolds. The generic type of device includes three types of applications: hardwire systems, inductance loop systems, and wireless systems.

(b) *Classification.* Class II.