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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.


§ 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 II.

[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]

§ 874.3310 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.

§ 874.3330 Master hearing aid.

(a) Identification. A master hearing aid is an electronic device intended to
simulate a hearing aid during audiometric testing. It has adjustable acoustic output levels, such as those for gain, output, and frequency response. The device is used to select and adjust a person’s wearable hearing aid.

(b) Classification. Class II.

§ 874.3375 Battery-powered artificial larynx.

(a) Identification. A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

(b) Classification. Class II.

§ 874.3380 Tinnitus masker.

(a) Identification. A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.

(b) Classification. Class II. The special control for this device is patient labeling regarding:

1. Hearing health care professional diagnosis, fitting of the device, and followup care,
2. Risks,
3. Benefits,
4. Warnings for safe use, and
5. Specifications.

§ 874.3395 Total ossicular replacement prosthesis.

(a) Identification. A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrane to the inner ear. The device is made of materials such as polytetrafluoroethylene with vitreous carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

(b) Classification. Class II.

§ 874.3450 Partial ossicular replacement prosthesis.

(a) Identification. A partial ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrane to the inner ear. The device is made of materials such as stainless steel, tantalum, polytetrafluoroethylene, polyethylene, polytetrafluoroethylene with carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

(b) Classification. Class II.

§ 874.3495 Total ossicular replacement prosthesis.

(a) Identification. A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrane to the inner ear. The device is made of materials such as polytetrafluoroethylene with vitreous carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

(b) Classification. Class II.

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.

(a) Identification. A prosthesis modification instrument for ossicular replacement surgery is a device intended for use by a surgeon to construct ossicular replacements. This generic type of device includes the ear, nose, and throat cutting block; wire crimper, wire bending die; wire closure forceps; piston cutting jib; gelfoam™ punch; wire cutting scissors; and ossicular finger vise.