

**§ 874.3375**

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 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 § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38800, July 25, 2001]

**§ 874.3400 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.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 17145, Mar. 31, 2000]

**§ 874.3430 Middle ear mold.**

(a) *Identification.* A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane. The device permits an ample air-filled cavity to be

**21 CFR Ch. I (4–1–10 Edition)**

maintained in the middle ear and promotes regeneration of the mucous membrane lining of the middle ear cavity. A middle ear mold is made of materials such as polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene, but does not contain porous polyethylene.

(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 wave 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, polytetrafluoroethylene with vitreous carbon fibers composite, 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.

(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 requirements of the quality system regulation 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. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 65 FR 2316, Jan. 14, 2000]

**§ 874.3620 Ear, nose, and throat synthetic polymer material.**

(a) *Identification*. Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the surgeon to conform to the patient's needs. This generic type of device is made of material such as polyamide mesh or foil and porous polyethylene.

(b) *Classification*. Class II.

**§ 874.3695 Mandibular implant facial prosthesis.**

(a) *Identification*. A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.

(b) *Classification*. Class II.

**§ 874.3730 Laryngeal prosthesis (Taub design).**

(a) *Identification*. A laryngeal prosthesis (Taub design) is a device intended to direct pulmonary air flow to the pharynx in the absence of the larynx, thereby permitting esophageal

speech. The device is interposed between openings in the trachea and the esophagus and may be removed and replaced each day by the patient. During phonation, air from the lungs is directed to flow through the device and over the esophageal mucosa to provide a sound source that is articulated as speech.

(b) *Classification*. Class II.

**§ 874.3760 Sacculotomy tack (Cody tack)**

(a) *Identification*. A sacculotomy tack (Cody tack) is a device that consists of a pointed stainless steel tack intended to be implanted to relieve the symptoms of vertigo. The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure.

(b) *Classification*. Class II.

**§ 874.3820 Endolymphatic shunt.**

(a) *Identification*. An endolymphatic shunt is a device that consists of a tube or sheet intended to be implanted to relieve the symptoms of vertigo. The device permits the unrestricted flow of excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. This device is made of polytetrafluoroethylene or silicone elastomer.

(b) *Classification*. Class II.

**§ 874.3850 Endolymphatic shunt tube with valve.**

(a) *Identification*. An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease.

(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document "Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA."

[67 FR 20894, Apr. 29, 2002]