

§ 874.3620

§ 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 (special controls). The device, when it is a voice amplification 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 84 FR 71813, Dec. 30, 2019]

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§ 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]

§ 874.3880 Tympanostomy tube.

(a) *Identification.* A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear

ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

(b) *Classification*. Class II.

§ 874.3900 Nasal dilator.

(a) *Identification*. A nasal dilator is a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow. The device decreases airway resistance and increases nasal airflow. The external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose; it acts with a pulling action to open the nares. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils; it acts by pushing the nostrils open or by gently pressing on the columella.

(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.

[64 FR 10949, Mar. 8, 1999]

§ 874.3930 Tympanostomy tube with semipermeable membrane.

(a) *Identification*. A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.

(b) *Classification*. Class II. The special control for this device is FDA's "Tympanostomy Tubes, Submission Guidance for a 510(k)."

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

§ 874.3950 Transcutaneous air conduction hearing aid system.

(a) *Identification*. A transcutaneous air conduction hearing aid system is a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. The device consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal.

(b) *Classification*. Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA." See § 874.1 for the availability of this guidance document.

[67 FR 67790, Nov. 7, 2002]

Subpart E—Surgical Devices

§ 874.4100 Epistaxis balloon.

(a) *Identification*. An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.

(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]

§ 874.4140 Ear, nose, and throat bur.

(a) *Identification*. An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (§ 874.4250) for incising or removing bone in the ear, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in