§ 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.

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

§ 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 skin adhesive is 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 §874.9.

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

§ 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 “Class II Special Controls Guidance Document: Tympanostomy Tubes, Submission Guidance for a 510(k).”

[64 FR 10949, Mar. 8, 1999]

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.

[67 FR 67790, Nov. 7, 2002]

§ 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 (§874.2250) for incising or removing bone in the ear, nose, or throat area.