Food and Drug Administration, HHS

§ 874.3900

§ 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, silicone 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