§ 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 (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Tympanostomy Tubes, Submission Guidance for a 510(k).” See §874.1 for the availability of this guidance document.

[67 FR 67790, Nov. 7, 2002]

§ 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]