

## Food and Drug Administration, HHS

## § 874.3

- 874.3320 Group hearing aid or group auditory trainer.
- 874.3330 Master hearing aid.
- 874.3375 Battery-powered artificial larynx.
- 874.3400 Tinnitus masker.
- 874.3430 Middle ear mold.
- 874.3450 Partial ossicular replacement prosthesis.
- 874.3495 Total ossicular replacement prosthesis.
- 874.3540 Prosthesis modification instrument for ossicular replacement surgery.
- 874.3620 Ear, nose, and throat synthetic polymer material.
- 874.3695 Mandibular implant facial prosthesis.
- 874.3730 Laryngeal prosthesis (Taub design).
- 874.3760 Sacculotomy tack (Cody tack).
- 874.3820 Endolymphatic shunt.
- 874.3850 Endolymphatic shunt tube with valve.
- 874.3880 Tympanostomy tube.
- 874.3900 Nasal dilator.
- 874.3930 Tympanostomy tube with semipermeable membrane.

### Subpart E—Surgical Devices

- 874.4100 Epistaxis balloon.
- 874.4140 Ear, nose, and throat bur.
- 874.4175 Nasopharyngeal catheter.
- 874.4250 Ear, nose, and throat electric or pneumatic surgical drill.
- 874.4350 Ear, nose, and throat fiberoptic light source and carrier.
- 874.4420 Ear, nose, and throat manual surgical instrument.
- 874.4490 Argon laser for otology, rhinology, and laryngology.
- 874.4500 Ear, nose, and throat microsurgical carbon dioxide laser.
- 874.4680 Bronchoscope (flexible or rigid) and accessories.
- 874.4710 Esophagoscope (flexible or rigid) and accessories.
- 874.4720 Mediastinoscope and accessories.
- 874.4750 Laryngostroboscope.
- 874.4760 Nasopharyngoscope (flexible or rigid) and accessories.
- 874.4770 Otoscope.
- 874.4780 Intranasal splint.
- 874.4800 Bone particle collector.

### Subpart F—Therapeutic Devices

- 874.5220 Ear, nose, and throat drug administration device.
- 874.5300 Ear, nose, and throat examination and treatment unit.
- 874.5350 Suction antichoke device.
- 874.5370 Tongs antichoke device.
- 874.5550 Powered nasal irrigator.
- 874.5800 External nasal splint.
- 874.5840 Antistammering device.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 51 FR 40389, Nov. 6, 1986, unless otherwise noted.

## Subpart A—General Provisions

### § 874.1 Scope.

(a) This part sets forth the classification of ear, nose, and throat devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an ear, nose, and throat device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

### § 874.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation