

Food and Drug Administration, HHS

§ 874.1

PART 874—EAR, NOSE, AND THROAT DEVICES

Subpart A—General Provisions

Sec.

874.1 Scope.

874.3 Effective dates of requirement for pre-market approval.

874.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

874.1050 Audiometer.

874.1060 Acoustic chamber for audiometric testing.

874.1070 Short increment sensitivity index (SISI) adapter.

874.1080 Audiometer calibration set.

874.1090 Auditory impedance tester.

874.1100 Earphone cushion for audiometric testing.

874.1120 Electronic noise generator for audiometric testing.

874.1325 Electroglottograph.

874.1500 Gustometer.

874.1600 Olfactory test device.

874.1800 Air or water caloric stimulator.

874.1820 Surgical nerve stimulator/locator.

874.1925 Toynbee diagnostic tube.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

874.3300 Hearing aid.

874.3305 Wireless air-conduction hearing aid.

874.3310 Hearing aid calibrator and analysis system.

874.3315 Tympanic membrane contact hearing aid.

874.3320 Group hearing aid or group auditory trainer.

874.3325 Self-fitting air-conduction hearing aid.

874.3330 Master hearing aid.

874.3340 Active implantable bone conduction hearing system.

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.

874.3950 Transcutaneous air conduction hearing aid system.

Subpart E—Surgical Devices

874.4100 Epistaxis balloon.

874.4140 Ear, nose, and throat bur.

874.4175 Nasopharyngeal catheter.

874.4180 Eustachian tube balloon dilation system.

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.

874.5900 External upper esophageal sphincter compression device.

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

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

EDITORIAL NOTE: Nomenclature changes to part 874 appear at 73 FR 35341, June 23, 2008.

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.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

[51 FR 40389, Nov. 6, 1986, as amended at 67 FR 67790, Nov. 7, 2002; 78 FR 18233, Mar. 26, 2013]

§ 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 be 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 under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a

regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 874.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the