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§ 820.198 with respect to complaint files.

§ 820.198, with respect to complaint files.


PART 874—EAR, NOSE, AND THROAT DEVICES

Subpart A—General Provisions

Sec.

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

§ 874.1 Scope.

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874.5840 Antistammering device.

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

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

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§ 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 (unless an exemption has been granted under section 515(b) 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.

(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 for 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 act.

FDA’s decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device’s safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical
purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[52 FR 32111, Aug. 25, 1987]

Subpart B—Diagnostic Devices

§ 874.1050 Audiometer.

(a) Identification. An audiometer or automated audiometer is an electroacoustic device that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

(b) Classification. Class II.

§ 874.1060 Acoustic chamber for audiometric testing.

(a) Identification. An acoustic chamber for audiometric testing is a room that is intended for use in conducting diagnostic hearing evaluations and that eliminates sound reflections and provides isolation from outside sounds.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1121, Jan. 16, 1996]

§ 874.1070 Short increment sensitivity index (SISI) adapter.

(a) Identification. A short increment sensitivity index (SISI) adapter is a device used with an audiometer in diagnostic hearing evaluations. A SISI adapter provides short periodic sound pulses in specific small decibel increments that are intended to be superimposed on the audiometer’s output tone frequency.

(b) Classification. Class II.

§ 874.1080 Audiometer calibration set.

(a) Identification. An audiometer calibration set is an electronic reference device that is intended to calibrate an audiometer. It measures the sound frequency and intensity characteristics that emanate from an audiometer earphone. The device consists of an acoustic cavity of known volume, a sound level meter, a microphone with calibration traceable to the National Bureau of Standards, oscillators, frequency counters, microphone amplifiers, and a recorder. The device can measure selected audiometer test frequencies at a given intensity level, and selectable audiometer attenuation settings at a given test frequency.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1121, Jan. 16, 1996]

§ 874.1090 Auditory impedance tester.

(a) Identification. An auditory impedance tester is a device that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. The device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of fluid in the middle ear cavity. The device is also used to measure the acoustic reflex threshold from contractions of the stapedial muscle, to monitor healing of tympanic membrane grafts or stapedectomies, or to monitor followup treatment for inflammation of the middle ear.

(b) Classification. Class II.

§ 874.1100 Earphone cushion for audiometric testing.

(a) Identification. An earphone cushion for audiometric testing is a device that is used to cover an audiometer earphone during audiometric testing to provide an acoustic coupling (sound
§ 874.1120 Electronic noise generator for audiometric testing.

(a) Identification. An electronic noise generator for audiometric testing is a device that consists of a swept frequency generator, an amplifier, and an earphone. It is intended to introduce a masking noise into the non-test ear during an audiometric evaluation. The device minimizes the non-test ear’s sensing of test tones and signals being generated for the ear being tested.

(b) Classification. Class II.

§ 874.1325 Electroglottograph.

(a) Identification. An electroglottograph is an AC-powered device that employs a pair of electrodes that are placed in contact with the skin on both sides of the larynx and held in place by a collar. It is intended to measure the electrical impedance of the larynx to aid in assessing the degree of closure of the vocal cords, confirm laryngeal diagnosis, aid behavioral treatment of voice disorders, and aid research concerning the laryngeal mechanism.

(b) Classification. Class II.

§ 874.1500 Gustometer.

(a) Identification. A gustometer is a battery-powered device that consists of two electrodes that are intended to be placed on both sides of the tongue at different taste centers and that provides a galvanic stimulus resulting in taste sensation. It is used for assessing the sense of taste.

(b) Classification. Class I. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180 with respect to general requirements concerning records, and § 820.198 with respect to complaint files.
§ 874.3450 Partial ossicular replacement prosthesis.

(a) Identification. A partial ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. The device is made of materials such as stainless steel, tantalum, polytetrafluoroethylene, polyethylene, polytetrafluoroethylene with carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

(b) Classification. Class II.
§ 874.3495 Total ossicular replacement prosthesis.
(a) Identification. A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrane to the inner ear. The device is made of materials such as polytetrafluoroethylene, polytetrafluoroethylene with vitreous carbon fibers composite, porous polyethylene, or from a combination of these materials.
(b) Classification. Class II.

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.
(a) Identification. A prosthesis modification instrument for ossicular replacement surgery is a device intended for use by a surgeon to construct ossicular replacements. This generic type of device includes the ear, nose, and throat cutting block; wire crimper; wire bending die; wire closure forceps; piston cutting jib; gelfoam™ punch; wire cutting scissors; and ossicular finger vise.
(b) Classification. Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.
[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987]

§ 874.3620 Ear, nose, and throat synthetic polymer material.
(a) Identification. Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is made of polyamide mesh or foil and porous polyethylene.
(b) Classification. Class II.

§ 874.3695 Mandibular implant facial prosthesis.
(a) Identification. A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.
(b) Classification. Class II.

§ 874.3730 Laryngeal prosthesis (Taub design).
(a) Identification. A laryngeal prosthesis (Taub design) is a device intended to direct pulmonary air flow to the pharynx in the absence of the larynx, thereby permitting esophageal speech. The device is interposed between openings in the trachea and the esophagus and may be removed and replaced each day by the patient. During phonation, air from the lungs is directed to flow through the device and over the esophageal mucosa to provide a sound source that is articulated as speech.
(b) Classification. Class II.

§ 874.3760 Sacculotomy tack (Cody tack)
(a) Identification. A sacculotomy tack (Cody tack) is a device that consists of a pointed stainless steel tack intended to be implanted to relieve the symptoms of vertigo. The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure.
(b) Classification. Class II.

§ 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
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§ 874.4175 Nasopharyngeal catheter.

(a) Identification. A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996]
§ 874.4250 Ear, nose, and throat electric or pneumatic surgical drill.

(a) Identification. An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur (§ 874.4140), for the controlled incision or removal of bone in the ear, nose, and throat area.

(b) Classification. Class II.

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(a) Identification. An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass of plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996]

§ 874.4420 Ear, nose, and throat manual surgical instrument.

(a) Identification. An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophagel dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tub; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal intrachono; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor; ear snare; ear spoon; ear suction tub; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; saccotomly tack inserter; vein press; wire ear loop; microure; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.

(b) Classification. Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in subpart E of part 807.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987]

§ 874.4490 Argon laser for otology, rhinology, and laryngology.

(a) Identification. The argon laser device for use in otology, rhinology, and laryngology is an electro-optical device which produces coherent, electromagnetic radiation with principal wavelength peaks of 488 and 514 nanometers. In otology, the device is used for the purpose of coagulating and vaporizing soft and fibrous tissues, including osseous tissue. In rhinology and laryngology, the device is used to coagulate and vaporize soft and fibrous tissues, but not including osseous tissues.

(b) Classification. Class II.

[58 FR 29534, May 21, 1993]

§ 874.4500 Ear, nose, and throat microsurgical carbon dioxide laser.

(a) Identification. An ear, nose, and throat microsurgical carbon dioxide laser is a device intended for the surgical excision of tissue from the ear, nose, and throat area. The device is used, for example, in microsurgical procedures to excise lesions and tumors of the vocal cords and adjacent areas.

(b) Classification. Class II.

§ 874.4680 Bronchoscope (flexible or rigid) and accessories.

(a) Identification. A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx
§ 874.4770 Otoscope.

(a) Identification. An otoscope is a device intended to allow inspection of the external ear canal and tympanic membrane under magnification. The device is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) Classification. Class II.

§ 874.4750 Laryngostroboscope.

(a) Identification. A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation. The device operates by focusing a stroboscopic light through a lens for direct or mirror reflected viewing of glottic action. The light and microphone that amplifies acoustic signals from the glottic area may or may not contact the patient.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 874.5220
provides illumination of the ear canal for observation by using an AC- or battery-powered light source and an optical magnifying system.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when used in the external ear canal.


Subpart F—Therapeutic Devices

§ 874.5220 Ear, nose, and throat drug administration device.

(a) Identification. An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 874.5300 Ear, nose, and throat examination and treatment unit.

(a) Identification. An ear, nose, and throat examination and treatment unit is an AC-powered device intended to support a patient during an otologic examination while providing specialized features for examination and treatment. The unit consists of a patient chair and table, drawers for equipment, suction and blowing apparatus, and receptacles for connection of specialized lights and examining instruments.

(b) Classification. Class I.

[55 FR 48440, Nov. 20, 1990]

§ 874.5350 Suction antichoke device.

(a) Identification. A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.

(b) Classification. Class III.

(c) Date PMA or notice or completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §874.3.

§ 874.5370 Tongs antichoke device.

(a) Identification. A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient. This generic type of device includes a plastic instrument with serrated ends that is inserted into the airway in a blind manner to grasp and extract foreign objects, and a stainless steel forceps with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §874.3.

§ 874.5550 Powered nasal irrigator.

(a) Identification. A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water. The device consists of a control unit and pump connected to a spray tube and nozzle.

(b) Classification. Class I.

[55 FR 48440, Nov. 20, 1990]

§ 874.5800 External nasal splint.

(a) Identification. An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.
§ 874.5840 Antistammering device.

(a) Identification. An antistammering device is a device that electronically generates a noise when activated or when it senses the user’s speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user’s involuntary hesitative or repetitive speech.

(b) Classification. Class I.