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subpart E of part 807 of this chapter subject to the limitations in §872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 872.6880 Preformed impression tray.

(a) Identification. A preformed impression tray is a metal or plastic device intended to hold impression material, such as alginate, to make an impression of a patient’s teeth or alveolar process (bony tooth sockets) to reproduce the structure of a patient’s teeth and gums.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 872.6890 Intraoral dental wax.

(a) Identification. Intraoral dental wax is a device made of wax intended to construct patterns from which custom made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is intended to make a pattern of a patient’s bite to make study models of the teeth.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation 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.

PART 874—EAR, NOSE, AND THROAT DEVICES

Subpart A—General Provisions

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Source: 51 FR 40389, Nov. 6, 1986, as amended at 67 FR 67790, Nov. 7, 2002

§ 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 under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a...
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§ 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 extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II 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 the intended use of a legally marketed device in that generic type of device; 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 healthcare professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; 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 deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;
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(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2315, Jan. 14, 2000]

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. Except for the otoacoustic emission device, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter; if it is in compliance with American National Standards Institute S3.6–1996, “Specification for Audiometers,” and subject to the limitations in §874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 64 FR 14831, Mar. 29, 1999]

§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.


§ 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 I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.


§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.


§ 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 audiomeric testing.

(a) Identification. An earphone cushion for audiomeric testing is a device that is used to cover an audiometer earphone during audiomeric testing to provide an acoustic coupling (sound connection path) between the audiometer earphone and the patient’s ear.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.1120 Electronic noise generator for audiomeric testing.

(a) Identification. An electronic noise generator for audiomeric 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 audiomeric 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.1600 Olfactory test device.

(a) Identification. An olfactory test device is used to determine whether an olfactory loss is present. The device includes one or more odorants that are presented to the patient’s nose to subjectively assess the patient’s ability to perceive odors.

(b) Classification. Class II (special controls). The special control for these devices is the FDA guidance document entitled “Class II Special Controls Guidance Document: Olfactory Test Device.” For the availability of this guidance document, see § 874.1(e). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. When indicated for the screening or diagnosis of diseases or conditions other than the loss of olfactory function, the device is not exempt from premarket notification procedures.

[71 FR 32835, June 7, 2006]

§ 874.1800 Air or water caloric stimulator.

(a) Identification. An air or water caloric stimulator is a device that delivers a stream of air or water to the ear canal at controlled rates of flow and temperature and that is intended for vestibular function testing of a patient’s body balance system. The vestibular stimulation of the semicircular
canals produce involuntary eye movements that are measured and recorded by a nystagmograph.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.


§ 874.1820 Surgical nerve stimulator/locator.

(a) Identification. A surgical nerve stimulator/locator is a device that is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.

(b) Classification. Class II.

§ 874.1925 Toynbee diagnostic tube.

(a) Identification. The toynbee diagnostic tube is a listening device intended to determine the degree of openness of the eustachian tube.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 874.3300 Hearing Aid.

(a) Identification. A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (§874.3320), master hearing aid (§874.3330), and tinnitus masker (§874.3400).

(b) Classification. (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

(2) Class II for the bone-conduction hearing aid.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]
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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 an 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.

§ 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 used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the surgeon to conform to the patient’s needs. This generic type of device is made of material such as 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 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.”

§ 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 with reduced nasal airflow. The device decreases airway resistance and increases nasal airflow. The external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose; it acts with a pulling action to open the nares. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils; it acts by pushing the nostrils open or by gently pressing on the columella.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.

[64 FR 10949, Mar. 8, 1999]

§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. The special control for this device is FDA’s “Tympanostomy Tubes, Submission Guidance for a 510(k).”

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

§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]
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§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.


§ 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 esophageal 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; nasal brush; nasal speculum; nasal ampulla; nasal thorn; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; tonsillar retractor; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissors; ear snare; ear spoon; ear suction tube; malleus rasper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossiculum holding clamp; sacculeotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.


§ 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...
§ 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 and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, 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.

§ 874.4710 Esophagoscope (flexible or rigid) and accessories.

(a) Identification. An esophagoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the esophagoscope and is intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus. When inserted, the device extends from the area of the hypopharynx to the stomach. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. 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.

§ 874.4720 Mediastinoscope and accessories.

(a) Identification. A mediastinoscope and accessories is a tubular tapered electrical endoscopic device with any of a group of accessory devices which attach to the mediastinoscope and is intended to examine or treat tissue in the area separating the lungs. The device is inserted transthoracically and is used in diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated. It 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.


§ 874.4760 Nasopharyngoscope (flexible or rigid) and accessories.

(a) Identification. A nasopharyngoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the nasopharyngoscope and is intended to examine or treat the nasal cavity and nasopharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. 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.
§ 874.4770  Otoscope.

(a) Identification. An otoscope is a device intended to allow inspection of the external ear canal and tympanic membrane under magnification. The device 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9 only when used in the external ear canal.


§ 874.4780  Intranasal splint.

(a) Identification. An intranasal splint is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. The intranasal splint is constructed from plastic, silicone, or absorbent material.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.

[64 FR 10949, Mar. 8, 1999]

§ 874.4800  Bone particle collector.

(a) Identification. A bone particle collector is a filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.

(b) Classification. Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.

§ 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 of completion of PDP is required. A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any suction antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a suction antichoke device that was in commercial distribution before May 28, 1976. Any other suction antichoke device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

§ 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 PDP is required. A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any tongs antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a tongs antichoke device that was in commercial distribution before May 28, 1976.

§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.

§ 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.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.

§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §874.9.
## PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

### Subpart A—General Provisions

Sec. 876.1 Scope.
876.3 Effective dates of requirement for premarket approval.
876.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

### Subpart B—Diagnostic Devices

876.1075 Gastroenterology-urology biopsy instrument.
876.1400 Stomach pH electrode.
876.1500 Endoscope and accessories.
876.1725 Gastrointestinal motility monitoring system.
876.1800 Urine flow or volume measuring system.

### Subpart C—Monitoring Devices

876.2040 Enuresis alarm.

### Subpart D—Prosthetic Devices

876.3350 Penile inflatable implant.
876.3630 Penile rigidity implant.
876.3750 Testicular prosthesis.

### Subpart E—Surgical Devices

876.4020 Fiberoptic light ureteral catheter.
876.4270 Colostomy rod.
876.4300 Endoscopic electro surgical unit and accessories.
876.4370 Gastroenterology-urology evacuator.
876.4400 Hemorrhoidal ligator.
876.4480 Electrohydraulic lithotripter.
876.4500 Mechanical lithotripter.
876.4530 Gastroenterology-urology fiberoptic retractor.
876.4560 Ribdam.
876.4590 Interlocking urethral sound.
876.4650 Water jet renal stone dislodger system.
876.4680 Ureteral stone dislodger.
876.4730 Manual gastroenterology-urology surgical instrument and accessories.
876.4770 Urethrotome.
876.4890 Urological table and accessories.

### Subpart F—Therapeutic Devices

876.5010 Biliary catheter and accessories.
876.5020 External penile rigidity devices.
876.5090 Suprapubic urological catheter and accessories.
876.5130 Urological catheter and accessories.
876.5140 Urological clamp for males.
876.5210 Enema kit.
876.5220 Colonic irrigation system.
876.5250 Urine collector and accessories.
876.5270 Implanted electrical urinary continence device.
876.5280 Implanted mechanical/hydraulic urinary continence device.
876.5310 Nonimplanted, peripheral electrical continence device.
876.5320 Nonimplanted electrical continence device.
876.5360 Esophageal dilator.
876.5450 Rectal dilator.
876.5470 Ureteral dilator.
876.5520 Urethral dilator.
876.5540 Blood access device and accessories.
876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.
876.5630 Peritoneal dialysis system and accessories.
876.5650 Water purification system for hemodialysis.
876.5680 Hemodialysis system and accessories.
876.5830 Continent ileostomy catheter.
876.5900 Ostomy pouch and accessories.
876.5920 Protective garment for incontinence.
876.5950 Peritoneo-venous shunt.
876.5970 Hernia support.
876.5980 Gastrointestinal tube and accessories.
876.5990 Extracorporeal shock wave lithotripter.

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

**SOURCE:** 48 FR 53023, Nov. 23, 1983, unless otherwise noted.

**Subpart A—General Provisions**

**EDITORIAL NOTE:** Nomenclature changes to part 876 appear at 73 FR 35341, June 23, 2008.

### §876.1 Scope.

(a) This part sets forth the classification of gastroenterology-urology devices intended for human use that are in commercial distribution.

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