

- (i) Information on how the device operates, including images or illustrations;
- (ii) A detailed summary of the device technical specifications;
- (iii) A warning which states that the use of this device is not a substitute for regular visits to a dentist for routine clinical care;
- (iv) Instructions on how to clean and maintain the device; and
- (v) The use life and disposal of the components of the device.

[89 FR 72321, Sept. 5, 2024]

§ 872.6870 Disposable fluoride tray.

(a) *Identification.* A disposable fluoride tray is a device made of styrofoam intended to apply fluoride topically to the teeth. To use the tray, the patient bites down on the tray which has been filled with a fluoride solution.

(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.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13831, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

§ 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.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13832, Apr. 5, 1989; 66 FR 38800, July 25, 2001]

§ 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.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38800, July 25, 2001]

PART 874—EAR, NOSE, AND THROAT DEVICES

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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 pre-market 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.

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(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 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 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

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where the former intended use was by health care 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;

(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 sig-

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nals 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 Standard 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.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38800, July 25, 2001]

§ 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.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2315, Jan. 14, 2000]

§ 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

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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.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38800, July 25, 2001]

§ 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 (special controls). The device, when it is a tympanometer or auditory impedance tester that complies with FDA-recognized consensus standard ANSI S3.39, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 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 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; 52 FR 18495, May 15, 1987, as amended at 52 FR 32111, Aug. 25, 1987; 65 FR 2315, Jan. 14, 2000]

§ 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 (special 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.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 874.1325 Electroglossograph.

(a) *Identification.* An electroglossograph 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 (special 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.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 874.1500 Gustometer.

(a) *Identification.* A gustometer is a battery-powered device that consists of two electrodes that are intended to be

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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 ves-

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tibular 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.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2316, Jan. 14, 2000]

§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 Air-conduction hearing aid.**

(a) *Identification.* An air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing that conducts sound to the ear through the air. An air-conduction hearing aid is subject to the requirements in §800.30 or §801.422 of this chapter, as applicable. The air-conduction hearing aid generic type excludes the group hearing aid or group auditory trainer, master hearing aid, and the tinnitus masker, regulated under §§874.3320, 874.3330, and 874.3400, respectively.

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

[87 FR 50762, Aug. 17, 2022]

§ 874.3302 Bone-conduction hearing aid.

(a) *Identification.* A bone-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that conducts sound to the inner ear through the skull. The non-implantable components of a bone-conduction hearing aid, such as the external sound processor, are subject to the requirements in § 801.422 of this chapter.

(b) *Classification.* Class II.

[87 FR 50762, Aug. 17, 2022]

§ 874.3305 Wireless air-conduction hearing aid.

(a) *Identification.* A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use. A wireless air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device;

(2) Performance testing must validate safety of exposure to non-ionizing radiation; and

(3) Performance data must validate wireless technology functions.

(c) *Premarket notification.* The wireless air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[76 FR 34846, June 15, 2011, as amended at 87 FR 50762, Aug. 17, 2022]

§ 874.3310 Hearing aid calibrator and analysis system.

(a) *Identification.* A hearing aid calibrator and analysis system is an electronic reference device intended to

calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. The device consists of an acoustic complex of known cavity volume, a sound level meter, a microphone, oscillators, frequency counters, microphone amplifiers, a distortion analyzer, a chart recorder, and a hearing aid test box.

(b) *Classification.* Class II (special 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.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 874.3315 Tympanic membrane contact hearing aid.

(a) *Identification.* A tympanic membrane contact hearing aid is a prescription wearable device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. A tympanic membrane contact hearing aid is subject to the requirements in § 801.422 of this chapter.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting components must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and must include:

(i) Mechanical integrity testing;

(ii) Electrical and thermal safety testing;

(iii) Software verification, validation, and hazard analysis;

(iv) Reliability testing consistent with expected device life;

(v) Electromagnetic compatibility testing; and

(vi) Validation testing of device output and mechanical force applied to the tympanic membrane in a clinically appropriate model.

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(3) Clinical performance testing must characterize any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(4) Professional training must include the ear impression procedure, correct placement, fitting, monitoring, care, and maintenance of the device.

(5) Labeling must include the following:

(i) A detailed summary of the adverse events and effectiveness outcomes from the clinical performance testing;

(ii) Detailed instructions on how to fit the device to the patient;

(iii) Instructions for periodic cleaning of any reusable components;

(iv) Information related to electromagnetic compatibility; and

(v) Patient labeling that includes:

(A) A patient card that identifies if a patient has been fitted with any non-self-removable components of the device and provides relevant information in cases of emergency;

(B) Information on how to correctly use and maintain the device;

(C) The potential risks and benefits associated with the use of the device; and

(D) Alternative treatments.

[81 FR 3326, Jan. 21, 2015, as amended at 87 FR 50762, Aug. 17, 2022]

§874.3320 Group hearing aid or group auditory trainer.

(a) *Identification.* A group hearing aid or group auditory trainer is a hearing aid that is intended for use in communicating simultaneously with one or more listeners having hearing impairment. The device is used with an associated transmitter microphone. It may be either monaural or binaural, and it provides coupling to the ear through either earphones or earmolds. The generic type of device includes three types of applications: hardwire systems, inductance loop systems, and wireless systems.

(b) *Classification.* Class II (special 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.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

21 CFR Ch. I (4-1-25 Edition)**§874.3325 Self-fitting air-conduction hearing aid.**

(a) *Identification.* A self-fitting air-conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings. A self-fitting air-conduction hearing aid is subject to the requirements in §800.30 or §801.422 of this chapter, as applicable.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must evaluate the effectiveness of the self-fitting strategy.

(2) Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested.

(3) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device.

(4) Software verification, validation, and hazard analysis must be performed.

(5) If the device incorporates wireless technology:

(i) Performance testing must validate safety of exposure to non-ionizing radiation; and

(ii) Performance data must validate wireless technology functions.

(6) Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.

[84 FR 57612, Oct. 28, 2019, as amended at 87 FR 50762, Aug. 17, 2022]

§874.3330 Master hearing aid.

(a) *Identification.* A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing. It has adjustable acoustic output levels, such as those for gain, output, and frequency response. The device is used to select and adjust a person's wearable hearing aid.

(b) *Classification.* Class II (special controls). The device is exempt from

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the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 874.3340 Active implantable bone conduction hearing system.

(a) *Identification.* An active implantable bone conduction hearing system is a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must characterize any adverse events observed during implantation and clinical use, and must also demonstrate that the device performs as intended under anticipated conditions of use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Performance data must validate force output in a clinically relevant model.

(ii) Impact testing in a clinically relevant anatomic model must be performed.

(iii) Mechanical integrity testing must be performed.

(iv) Reliability testing consistent with expected device life must be performed.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Performance data must demonstrate the wireless compatibility,

electromagnetic compatibility, and electrical safety of the device.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Labeling must include:

(i) A summary of clinical testing conducted with the device that includes a summary of device-related complications and adverse events;

(ii) Instructions for use;

(iii) A surgical guide for implantation, which includes instructions for imaging to assess bone dimensions;

(iv) A shelf life, for device components provided sterile;

(v) A patient identification card; and

(vi) A patient user manual.

[83 FR 54009, Oct. 26, 2018]

§ 874.3375 Battery-powered artificial larynx.

(a) *Identification.* A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of 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 the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38800, July 25, 2001]

§ 874.3400 Tinnitus masker.

(a) *Identification.* A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.

(b) *Classification.* Class II. The special control for this device is patient labeling regarding:

(1) Hearing health care professional diagnosis, fitting of the device, and followup care,

(2) Risks,

(3) Benefits,

(4) Warnings for safe use, and

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(5) Specifications.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 17145, Mar. 31, 2000]

§ 874.3430 Middle ear mold.

(a) *Identification.* A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane. The device permits an ample air-filled cavity to be maintained in the middle ear and promotes regeneration of the mucous membrane lining of the middle ear cavity. A middle ear mold is made of materials such as polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene, but does not contain porous polyethylene.

(b) *Classification.* Class II (special 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.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 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

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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 (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. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 65 FR 2316, Jan. 14, 2000]

§ 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

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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 (special controls). The device, when it is a voice amplification device, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 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 poly-

tetrafluoroethylene 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."

[67 FR 20894, Apr. 29, 2002]

§ 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, silicon 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

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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 17145, Mar. 31, 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. A transcutaneous air conduction hearing aid system is subject to the requirements in § 801.422 of this chapter.

(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

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FDA." See § 874.1 for the availability of this guidance document.

[67 FR 67790, Nov. 7, 2002, as amended at 87 FR 50762, Aug. 17, 2022]

Subpart E—Surgical Devices

§ 874.4100 Epistaxis balloon.

(a) *Identification.* An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.

(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]

§ 874.4140 Ear, nose, and throat bur.

(a) *Identification.* An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (§ 874.4250) for incising or removing bone in the ear, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(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.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38800, July 25, 2001]

§ 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 (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 874.4180 Eustachian tube balloon dilation system.

(a) *Identification.* A Eustachian tube balloon dilation system is a prescription device that includes a flexible catheter attached to an inflatable balloon. The system is intended for use in dilating the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Mechanical testing, including tensile and flexural testing of catheter joints and materials.

(ii) Durability testing, including fatigue and burst pressure testing of the balloon materials and components.

(iii) Inflation and deflation characterization testing, including time and pressure measurements, and leak testing of the balloon.

(iv) Verification testing of safety features built into the device must be performed, including the characterization of catheter geometries and distal tip insertion limitation mechanisms.

(2) Simulated use testing in a clinically relevant model must demonstrate the reliability of the device to remain mechanically functional throughout the anticipated conditions of use, and validate that the design features limit access to only the cartilaginous portion of the Eustachian tube.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device.

(5) Performance data must support shelf life by demonstrating continued sterility of the device, package integrity, and device functionality over the identified shelf life.

(6) Training must include simulated use on cadavers to ensure users can follow the instructions for use to allow safe use of the device.

(7) Labeling must include:

(i) Detailed instructions for use.

(ii) A detailed summary of the device technical parameters, including maximum allowed inflation pressure, allowable catheter geometries, and available balloon sizes.

(iii) A shelf life.

[81 FR 73041, Oct. 24, 2016]

§ 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 or 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 the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 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

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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; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; autom reforator; 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 scissor; ear snare; ear spoon; ear suction tube; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossicu holding clamp; sacculotomy 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.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 65 FR 2316, Jan. 14, 2000; 72 FR 17400, Apr. 9, 2007]

§ 874.4450 Powered insertion system for a cochlear implant electrode array.

(a) *Identification*. A powered insertion system for a cochlear implant electrode array is a prescription device used to assist in placing an electrode array into the cochlea.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including evaluation of all adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

(i) Verification of cochlear implant attachment force, release force, and insertion speed;

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(ii) Testing to demonstrate the device does not damage or degrade the cochlear implant (including the lead and array portions of the cochlear implant); and

(iii) Comparison testing with manual insertion to evaluate:

(A) Differences in cochlear implant array insertion force associated with use of the device; and

(B) Intracochlear placement of the cochlear implant array (intended scala placement and array insertion depth, together with minimal array tip foldover and cochlear scala translocation).

(3) Usability testing in a simulated hospital environment with an anatomically relevant model (e.g., cadaver testing) that evaluates the following:

(i) Successful use to aid in placement of the electrode array into the cochlea; and

(ii) Harms caused by use errors observed.

(4) Changes in cochlear implant compatibility are determined to significantly affect the safety or effectiveness of the device and must be validated through performance testing or a rationale for omission of any testing.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(7) The patient-contacting components of the device must be demonstrated to be sterile and non-pyrogenic.

(8) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(9) Software verification, validation, and hazard analysis must be performed for any software components of the device.

(10) Labeling must include:

(i) The recommended training for the safe use of the device;

(ii) Summary of the relevant clinical and non-clinical testing pertinent to use of the device with compatible electrode arrays; and

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(iii) A shelf life.

[88 FR 979, Jan. 6, 2023]

§ 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 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, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube,

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

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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.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 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 nasal pharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel and flexible plastic. This generic type of device includes the antroscope, nasopharyngolaryngoscope, nasinoscopic, nasoscope, postrhinoscope, rhinoscope, salpingoscope, 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

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subject to the limitations in § 874.9 only when used in the external ear canal.

[55 FR 48440, Nov. 20, 1990, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 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.

[64 FR 10949, Mar. 8, 1999]

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 (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. 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

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chapter, 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. 6, 1986, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

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

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2316, Jan. 14, 2000]

§ 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.

[51 FR 40389, Nov. 6, 1986, as amended at 64 FR 18329, Apr. 14, 1999; 65 FR 2316, Jan. 14, 2000]

§ 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. Any other tongs antichoke device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[51 FR 40389, Nov. 6, 1986, as amended at 64 FR 18329, Apr. 14, 1999]

§ 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.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2316, Jan. 14, 2000]

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§ 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.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 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 hesitant 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.

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

§ 874.5900 External upper esophageal sphincter compression device.

(a) *Identification.* An external upper esophageal sphincter compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting components must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mechanical integrity testing (e.g., tensile strength testing, fatigue testing) and

(ii) Shelf life testing.

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(3) The technical specifications must include pressure measurement accuracy to characterize device performance.

(4) Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include the following:

(i) Appropriate warnings and precautions,

(ii) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events,

(iii) Detailed instructions on how to fit the device to the patient, and

(iv) Instructions for reprocessing of any reusable components.

(6) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, and adverse effects/complications,

(ii) Information on how to correctly wear the device,

(iii) The potential risks and benefits associated with the use of the device,

(iv) Alternative treatments, and

(v) Reprocessing instructions.

[80 FR 46194, Aug. 4, 2015]

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

876.1050 Endoscopic transhepatic venous access needle.

876.1075 Gastroenterology-urology biopsy instrument.

876.1080 Gastroenterology-urology accessories to a biopsy instrument.

876.1300 Ingestible telemetric gastrointestinal capsule imaging system.

876.1310 Magnetically maneuvered capsule endoscopy system.

876.1330 Colon capsule endoscopy system.

876.1400 Stomach pH electrode.