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872.6880 Preformed impression tray.
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SOURCE: 52 FR 30097, Aug. 12, 1987, unless otherwise noted.
EDITORIAL NOTE: Nomenclature changes to part 872 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions
§ 872.1 Scope.
(a) This part sets forth the classification of dental devices intended for human use that are in commercial distribution.
(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions 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, a dental device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.
(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.
(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html.


§ 872.3 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
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§ 872.9 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 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 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
§ 872.1500 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).

Subpart B—Diagnostic Devices

§ 872.1500 Gingival fluid measurer.

(a) Identification. A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(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.


§ 872.1520 Pulp tester.

(a) Identification. A pulp tester is an AC or battery powered device intended to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.

(b) Classification. Class II.

§ 872.1570 Electrode gel for pulp testers.

(a) Identification. An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.

(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.


§ 872.1540 Caries detection device.

(a) Identification. The caries detection device is a device intended to show the existence of decay in a patient’s tooth by use of electrical current.

(b) Classification. Class II.

§ 872.1545 Laser fluorescence caries detection device.

(a) Identification. A laser fluorescence caries detection device is a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.

(b) Classification. Class II, subject to the following special controls:

1. Sale, distribution, and use of this device are restricted to prescription use in accordance with §801.109 of this chapter;

2. Premarket notifications must include clinical studies, or other relevant information, that demonstrates that the device aids in the detection of tooth decay by measuring increased laser induced fluorescence; and

3. The labeling must include detailed use instructions with precautions that urge users to:
(i) Read and understand all directions before using the device,
(ii) Store probe tips under proper conditions,
(iii) Properly sterilize the emitter-detector handpick before each use, and
(iv) Properly maintain and handle the instrument in the specified manner and condition.

§ 872.1800 Extraoral source x-ray system.
(a) Identification. An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.
(b) Classification. Class II.

§ 872.1810 Intraoral source x-ray system.
(a) Identification. An intraoral source x-ray system is an electrically powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.
(b) Classification. Class II.

§ 872.1820 Dental x-ray exposure alignment device.
(a) Identification. A dental x-ray exposure alignment device is a device intended to position x-ray film and to align the examination site with the x-ray beam.
(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.

§ 872.1830 Cephalometer.
(a) Identification. A cephalometer is a device used in dentistry during x-ray procedures. The device is intended to place and to hold a patient’s head in a standard position during dental x-rays.
(b) Classification. Class II.

§ 872.1840 Dental x-ray position indicating device.
(a) Identification. A dental x-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the x-ray beam and to restrict the dimensions of the dental x-ray field by limiting the size of the primary x-ray beam.
(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.

§ 872.1850 Lead-lined position indicator.
(a) Identification. A lead-lined position indicator is a cone-shaped device lined with lead that is attached to a dental x-ray tube and intended to aid in positioning the tube, to prevent the misfocusing of the x-rays by absorbing divergent radiation, and to prevent leakage of radiation.
(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.

§ 872.1870 Sulfide detection device.
(a) Identification. A sulfide detection device is a device consisting of an AC-powered control unit, probe handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.
§ 872.1905 Dental x-ray film holder.

(a) Identification. A dental x-ray film holder is a device intended to position and to hold x-ray film inside the mouth.

(b) Classification. Class II (special controls) prescription use in accordance with §801.109 of this chapter; conformance with recognized standards of biocompatibility, electrical safety, and sterility; clinical and analytical performance testing, and proper labeling.

[63 FR 59717, Nov. 5, 1998]

§ 872.2050 Dental sonography device.

(a) Dental sonography device for monitoring—(1) Identification. A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) Classification. Class I. 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 also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exceptions of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 872.2060 Jaw tracking device.

(a) Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla—(1) Identification. A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

(2) Classification. Class I (general controls). The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to §872.9.

(b) Jaw tracking device for interpretation of mandibular jaw positions for the diagnosis—(1) Identification. A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to

[68 FR 67367, Dec. 2, 2003]
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be considered with data from other diagnostic components.

(2) Classification. Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.”

[68 FR 67367, Dec. 2, 2003]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 872.3060 Noble metal alloy.

(a) Identification. A noble metal alloy is a device composed primarily of noble metals, such as gold, palladium, platinum, or silver, that is intended for use in the fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.

(b) Classification. Class II (special controls). The special control for these devices is FDA’s “Class II Special Controls Guidance Document: Dental Noble Metal Alloys.” The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9. See §872.1(e) for availability of guidance information.

[69 FR 51766, Aug. 23, 2004]

§ 872.3070 Dental amalgam, mercury, and amalgam alloy.

(a) Identification. Dental amalgam is a device that consists of a combination of elemental mercury, supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy.” See §872.1(e) for the availability of this guidance document.

[74 FR 38714, Aug. 4, 2009]

§ 872.3080 Mercury and alloy dispenser.

(a) Identification. A mercury and alloy dispenser is a device with a spring-activated valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets.

(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.


§ 872.3100 Dental amalgamator.

(a) Identification. A dental amalgamator is a device, usually AC-powered, intended to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The mixed dental amalgam material is intended for filling dental caries.

(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.


§ 872.3110 Dental amalgam capsule.

(a) Identification. A dental amalgam capsule is a container device in which sliver alloy is intended to be mixed with mercury to form dental amalgam.

(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.


§ 872.3130 Preformed anchor.

(a) Identification. A preformed anchor is a device made of austenitic alloys or alloys containing 75 percent or greater
§ 872.3140 Resin applicator.

(a) Identification. A resin applicator is a brushlike device intended for use in spreading dental resin on a tooth during application of tooth shade 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 § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 872.3150 Articulator.

(a) Identification. An articulator is a mechanical device intended to simulate movements of a patient’s upper and lower jaws. Plaster casts of the patient’s teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient’s jaws. An articulator is intended to fit dentures or provide orthodontic treatment.

(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, the device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.
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§872.3300 Hydrophilic resin coating for dentures.

(a) Identification. A hydrophilic resin coating for dentures is a device that consists of a water-retaining polymer that is intended to be applied to the base of a denture before the denture is inserted into the patient’s mouth to improve denture retention and comfort.

(b) Classification. Class II.
§ 872.3310 Coating material for resin fillings.

(a) Identification. A coating material for resin fillings is a device intended to be applied to the surface of a restorative resin dental filling to attain a smooth, glaze-like finish on the surface of the filling.

(b) Classification. Class II.

§ 872.3330 Preformed crown.

(a) Identification. A preformed crown is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is intended for use as a functional restoration until a permanent crown is constructed. The device also may be intended for use as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.

(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.


§ 872.3350 Gold or stainless steel cusp.

(a) Identification. A gold or stainless steel cusp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group or stainless steel intended to provide a permanent cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) between the teeth and a removable denture.

(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.


§ 872.3360 Preformed cusp.

(a) Identification. A preformed cusp is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be used as a temporary cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) before permanent restoration of a tooth.

(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.


§ 872.3400 Karaya and sodium borate with or without acacia denture adhesive.

(a) Identification. A karaya and sodium borate with or without acacia denture adhesive is a device composed of karaya and sodium borate with or without acacia intended to be applied to the base of a denture before the denture is inserted into patient’s mouth to improve denture retention and comfort.

(b) Classification. (1) Class I (general controls) if the device contains less than 12 percent by weight of sodium borate. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §872.9.

(2) Class III if the device contains 12 percent or more by weight of sodium borate.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976. Any other karaya and sodium borate with or without acacia denture adhesive shall have an approved PMA or
a declared completed PDP in effect before being placed in commercial distribution.


§ 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.

(a) Identification. An ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive is a device containing ethylene oxide homopolymer and/or carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient’s mouth to improve denture retention and comfort.

(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.


§ 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

(a) Identification. A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer intended to be applied to the base of a denture before the denture is inserted in a patient’s mouth to improve denture retention and comfort.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976. Any other carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.

(a) Identification. Ethylene oxide homopolymer and/or karaya denture adhesive is a device composed of ethylene oxide homopolymer and/or karaya intended to be applied to the base of a denture before the denture is inserted in a patient’s mouth to improve denture retention and comfort.

(b) Classification. (1) Class I if the device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. The device is intended to be discarded following 1 day’s use. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §872.9.


§ 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

(a) Identification. A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) intended to be applied to the base of a denture before the denture is inserted in a patient’s mouth to improve denture retention and comfort.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a

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polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyacrylamide polymer (modified cationic) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

(a) Identification. A carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt intended to be applied to the base of a denture before the denture is inserted in a patient’s mouth to improve denture retention and comfort.

(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.

§ 872.3500 Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.

(a) Identification. Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient’s mouth to improve denture retention and comfort.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 872.3520 OTC denture cleanser.

(a) Identification. An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste that is intended to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient’s mouth when the appliance is cleaned.

(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.

§ 872.3530 Mechanical denture cleaner.

(a) Identification. A mechanical denture cleaner is a device, usually AC-powered, that consists of a container for mechanically agitating a denture cleansing solution. The device is intended to clean a denture by submersion in the agitating cleansing solution in the container.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in
§ 872.3540 OTC denture cushion or pad.

(a) Identification. An OTC denture cushion or pad is a prefabricated or noncustom made disposable device that is intended to improve the fit of a loose or uncomfortable denture, and may be available for purchase over-the-counter.

(b) Classification.

(1) Class I if the device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. The device is intended to be discarded following 1 day’s use. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

(2) Class II if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (b)(1) of this section. The special controls for this device are FDA’s:

(i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and

(ii) “OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.”


§ 872.3550 OTC denture reliner.

(a) Identification. An OTC denture reliner is a device consisting of a material such as plastic resin that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is intended to replace a worn denture lining and may be available for purchase over the counter.

(b) Classification. Class II. The special controls for this device are FDA’s:

(1) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and

(2) “OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.”


§ 872.3560 OTC denture repair kit.

(a) Identification. An OTC denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device may be available for purchase over-the-counter.

(b) Classification. Class II. The special controls for this device are FDA’s:

(1) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and

(2) “OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.”

[52 FR 30097, Aug. 12, 1987, as amended at 65 FR 17144, Mar. 31, 2000]

§ 872.3570 Preformed gold denture tooth.

(a) Identification. A preformed gold denture tooth is a device composed of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use as a tooth or a portion of a tooth in a fixed or removable partial denture.

(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.


§ 872.3580 Preformed plastic denture tooth.

(a) Identification. A preformed plastic denture tooth is a prefabricated device, composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.

(b) Classification. Class II.
§ 872.3600 Partially fabricated denture kit.

(a) Identification. A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient’s mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base.

(b) Classification. Class II. The special controls for this device are FDA’s:


2. “OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.”

[52 FR 30097, Aug. 12, 1987, as amended at 65 FR 17144, Mar. 31, 2000]

§ 872.3630 Endosseous dental implant abutment.

(a) Identification. An endosseous dental implant abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

(b) Classification. Class II (special controls). The guidance document entitled “Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments” will serve as the special control. (See §872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval). The device is classified as class III if it is a blade-form endosseous dental implant.

[69 FR 26304, May 12, 2004]

§ 872.3640 Endosseous dental implant.

(a) Identification. An endosseous dental implant is a device made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient’s chewing function.

(b) Classification. (1) Class II (special controls). The device is classified as class II if it is a root-form endosseous dental implant. The root-form endosseous dental implant is characterized by four geometrically distinct types: Basket, screw, solid cylinder, and hollow cylinder. The guidance document entitled “Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments” will serve as the special control. (See §872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval). The device is classified as class III if it is a blade-form endosseous dental implant.

[69 FR 26304, May 12, 2004]

§ 872.3645 Subperiosteal implant material.

(a) Identification. Subperiosteal implant material is a device composed of titanium or cobalt chrome molybdenum intended to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for prostheses, such as dentures.

(b) Classification. Class II.

§ 872.3660 Impression material.

(a) Identification. Impression material is a device composed of materials such as alginate or polysulfide intended to be placed on a preformed impression tray and used to reproduce the structure of a patient’s teeth and gums. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

(b) Classification. Class II (Special Controls).


§ 872.3661 Optical Impression Systems for CAD/CAM.

(a) Identification. An optical impression system for computer assisted design and manufacturing (CAD/CAM) is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by
§ 872.3670 Resin impression tray material.

(a) Identification. Resin impression tray material is a device intended for use in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray for use in cases in which a preformed impression tray is not suitable, such as the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient’s teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient’s mouth to make an impression, from which a final, more precise, model of the patient’s mouth is cast.

(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 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

§ 872.3680 Polytetrafluoroethylene (PTFE) vitreous carbon materials.

(a) Identification. Polytetrafluoroethylene (PTFE) vitreous carbon material is a device composed of polytetrafluoroethylene (PTFE) vitreous carbon intended for use in maxillofacial alveolar ridge augmentation (building up the upper or lower jaw area that contains the sockets in which teeth are rooted) or intended to coat metal surgical implants to be placed in the alveoli (sockets in which the teeth are rooted) or the temporomandibular joints (the joint between the upper and lower jaws).

(b) Classification. Class II. [52 FR 30097, Aug. 12, 1987; 52 FR 34456, Sept. 11, 1987]

§ 872.3690 Tooth shade resin material.

(a) Identification. Tooth shade resin material is a device composed of materials such as bisphenol-A glycidyl methacrylate (Bis-GMA) intended to restore carious lesions or structural defects in teeth.

(b) Classification. Class II. [52 FR 30097, Aug. 12, 1987]

§ 872.3710 Base metal alloy.

(a) Identification. A base metal alloy is a device composed primarily of base metals, such as nickel, chromium, or cobalt, that is intended for use in fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Dental Base Metal Alloys.” 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. See §872.1(e) for availability of guidance information. [69 FR 51766, Aug. 23, 2004]

§ 872.3730 Pantograph.

(a) Identification. A pantograph is a device intended to be attached to a patient’s head to duplicate lower jaw
movements to aid in construction of restorative and prosthetic dental devices. A marking pen is attached to the lower jaw component of the device and, as the patient’s mouth opens, the pen records on graph paper the angle between the upper and the lower jaw.

(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.

§ 872.3740 Retentive and splinting pin.

(a) **Identification.** A retentive and splinting pin is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.

(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.

§ 872.3750 Bracket adhesive resin and tooth conditioner.

(a) **Identification.** A bracket adhesive resin and tooth conditioner is a device composed of an adhesive compound, such as polymethylmethacrylate, intended to cement an orthodontic bracket to a tooth surface.

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

§ 872.3760 Denture relining, repairing, or rebasing resin.

(a) **Identification.** A denture relining, repairing, or rebasing resin is a device composed of materials such as polymethylmethacrylate, intended to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. This device is not available for over-the-counter (OTC) use.

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

§ 872.3765 Pit and fissure sealant and conditioner.

(a) **Identification.** A pit and fissure sealant and conditioner is a device composed of resin, such as polymethylmethacrylate, intended for use primarily in young children to seal pit and fissure depressions (faults in the enamel) in the biting surfaces of teeth to prevent cavities.

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

§ 872.3770 Temporary crown and bridge resin.

(a) **Identification.** A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.

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

§ 872.3810 Root canal post.

(a) **Identification.** A root canal post is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be cemented into the root canal of a tooth to stabilize and support a restoration.

(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.

§ 872.3820 Root canal filling resin.

(a) **Identification.** A root canal filling resin is a device composed of material, such as methylmethacrylate, intended for use during endodontic therapy to fill the root canal of a tooth.

(b) **Classification.** (1) Class II if chloroform is not used as an ingredient in the device.

(2) Class III if chloroform is used as an ingredient in the device.
§ 872.3910 Backing and facing for an artificial tooth.

(a) Identification. A backing and facing for an artificial tooth is a device made of a material, such as titanium, intended to be inserted through the root canal into the upper or lower jaw bone to stabilize a tooth.

(b) Classification. Class II.

§ 872.3900 Posterior artificial tooth with a metal insert.

(a) Identification. A posterior artificial tooth with a metal insert is a porcelain device with an insert made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to replace a natural tooth. The device is attached to surrounding teeth by a bridge and is intended to provide both an improvement in appearance and functional occlusion (bite).

(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.


§ 872.3890 Endodontic stabilizing splint.

(a) Identification. An endodontic stabilizing splint is a device made of a material, such as titanium, intended to be inserted through the root canal into the upper or lower jaw bone to stabilize a tooth.

(b) Classification. Class II.

§ 872.3850 Gutta percha.

(a) Identification. Gutta percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.

(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.


§ 872.3840 Endodontic silver point.

(a) Identification. An endodontic silver point is a device made of silver intended for use during endodontic therapy to fill permanently the root canal of a tooth.

(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.


§ 872.3830 Endodontic paper point.

(a) Identification. An endodontic paper point is a device made of paper intended for use during endodontic therapy to dry, or apply medication to, the root canal of a tooth.

(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.

§ 872.3920 Porcelain tooth.

(a) Identification. A porcelain tooth is a prefabricated device made of porcelain powder for clinical use (§872.6660) intended for use in construction of fixed or removable prostheses, such as crowns and partial dentures.

(b) Classification. Class II.

§ 872.3930 Bone grafting material.

(a) Identification. Bone grafting material is a material such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

(b) Classification. (1) Class II (special controls) for bone grafting materials that do not contain a drug that is a therapeutic biologic. The special control is FDA’s “Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices.” (See §872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval) for bone grafting materials that contain a drug that is a therapeutic biologic. Bone grafting materials that contain a drug that is a therapeutic biologic, such as biological response modifiers, require premarket approval.

(c) Date PMA or notice of completion of a PDP is required. Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 872.3940 Total temporomandibular joint prosthesis.

(a) Identification. A total temporomandibular joint prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976. Any other total temporomandibular joint prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 872.3950 Glenoid fossa prosthesis.

(a) Identification. A glenoid fossa prosthesis is a device that is intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any glenoid fossa prosthesis that was in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to a glenoid fossa prosthesis that was in commercial distribution before May 28, 1976. Any other glenoid fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 872.4130 Intraoral dental drill.

(a) Identification. An intraoral dental drill is a rotary device intended to be attached to a dental handpiece to drill holes in teeth to secure cast or preformed pins to retain operative dental appliances.
§ 872.4200 Dental handpiece and accessories.

(a) Identification. A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

(b) Classification. Class I.

[55 FR 48439, Nov. 20, 1990]

§ 872.4465 Gas-powered jet injector.

(a) Identification. A gas-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.

(b) Classification. Class II.


§ 872.4535 Dental diamond instrument.

(a) Identification. A dental diamond instrument is an abrasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts a tooth.

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

§ 872.4600 Intraoral ligature and wire lock.
(a) Identification. An intraoral ligature and wire lock is a metal device intended to constrict fractured bone segments in the oral cavity. The bone segments are stabilized by wrapping the ligature (wire) around the fractured bone segments and locking the ends together.
(b) Classification. Class II.

§ 872.4620 Fiber optic dental light.
(a) Identification. A fiber optic dental light is a device that is a light, usually AC-powered, that consists of glass or plastic fibers which have special optical properties. The device is usually attached to a dental handpiece and is intended to illuminate a patient’s oral structures.
(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.

§ 872.4630 Dental operating light.
(a) Identification. A dental operating light, including the surgical headlight, is an AC-powered device intended to illuminate oral structures and operating areas.
(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.

§ 872.4730 Dental injecting needle.
(a) Identification. A dental injecting needle is a slender, hollow metal device with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs.
(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.

§ 872.4760 Bone plate.
(a) Identification. A bone plate is a metal device intended to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.
(b) Classification. Class II.

§ 872.4840 Rotary scaler.
(a) Identification. A rotary scaler is an abrasive device intended to be attached to a powered handpiece to remove calculus deposits from teeth during dental cleaning and periodontal (gum) therapy.
(b) Classification. Class II.

§ 872.4850 Ultrasonic scaler.
(a) Identification. An ultrasonic scaler is a device intended for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.
(b) Classification. Class II.

§ 872.4880 Intraosseous fixation screw or wire.
(a) Identification. An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement.
(b) Classification. Class II.

§ 872.4920 Dental electrosurgical unit and accessories.
(a) Identification. A dental electrosurgical unit and accessories is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. This device is intended to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into
the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.

(b) Classification. Class II.

Subpart F—Therapeutic Devices

§ 872.5410 Orthodontic appliance and accessories.

(a) Identification. An orthodontic appliance and accessories is a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire.

(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.


§ 872.5470 Orthodontic plastic bracket.

(a) Identification. An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.

(b) Classification. Class II.

§ 872.5500 Extraoral orthodontic headgear.

(a) Identification. An extraoral orthodontic headgear is a device intended for use with an orthodontic appliance to exert pressure on the teeth from outside the mouth. The headgear has a strap intended to wrap around the patient’s neck or head and an inner bow portion intended to be fastened to the orthodontic appliance in the patient’s mouth.

(b) Classification. Class II.

§ 872.5525 Preformed tooth positioner.

(a) Identification. A preformed tooth positioner is a plastic device that is an impression of a perfected bite intended to prevent a patient’s teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The patient bites down on the device for several hours a day to force the teeth into a final position or to maintain the teeth in their corrected position.

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


§ 872.5550 Teething ring.

(a) Identification. A teething ring is a device intended for use by infants for medical purposes to soothe gums during the teething process.

(b)(1) Classification. Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

(2) Class II if the teething ring contains a fluid, such as water.


§ 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

(a) Identification. Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.

(b) Classification. Class II (special controls). The special control for these devices is the FDA guidance document entitled “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA.”

[67 FR 68512, Nov. 12, 2002]
§ 872.5580 Oral rinse to reduce the adhesion of dental plaque.

(a) Identification. The device is assigned the generic name oral rinse to reduce the adhesion of dental plaque and is identified as a device intended to reduce the presence of bacterial plaque on teeth and oral mucosal surfaces by physical means. The device type includes those devices that act by reducing the attachment and inhibiting the growth of bacterial plaque.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque.” See §872.1(e) for the availability of this guidance document.

[70 FR 55028, Sept. 20, 2005]

Subpart G—Miscellaneous Devices

§ 872.6010 Abrasive device and accessories.

(a) Identification. An abrasive device and accessories is a device constructed of various abrasives, such as diamond chips, that are glued to shellac-based paper. The device is intended to remove excessive restorative materials, such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece. The device includes the abrasive disk, guard for an abrasive disk, abrasive point, polishing agent strip, and polishing wheel.

(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.


§ 872.6030 Oral cavity abrasive polishing agent.

(a) Identification. An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).

(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.


§ 872.6050 Saliva absorber.

(a) Identification. A saliva absorber is a device made of paper or cotton intended to absorb moisture from the oral cavity during dental procedures.

(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.


§ 872.6070 Ultraviolet activator for polymerization.

(a) Identification. An ultraviolet activator for polymerization is a device that produces ultraviolet radiation intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod.

(b) Classification. Class II.

§ 872.6080 Airbrush.

(a) Identification. An airbrush is an AC-powered device intended for use in conjunction with articulation paper. The device uses air-driven particles to...
§ 872.6100 Anesthetic warmer.

(a) Identification. An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are intended to be placed to warm them prior to administration of the anesthetic.

(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.

§ 872.6200 Base plate shellac.

(a) Identification. Base plant shellac is a device composed of shellac intended to rebuild the occlusal rim of full or partial dentures.

(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.
Food and Drug Administration, HHS

§ 872.6570 Impression tube.

(a) Identification. An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.

(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 §872.9.


§ 872.6390 Dental floss.

(a) Identification. Dental floss is a string-like device made of cotton or other fibers intended to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.

(b) Classification. Class II.


§ 872.6350 Ultraviolet detector.

(a) Identification. An ultraviolet detector is a device intended to provide a source of ultraviolet light which is used to identify otherwise invisible material, such as dental plaque, present in or on teeth.

(b) Classification. Class II.


§ 872.6475 Heat source for bleaching teeth.

(a) Identification. A heat source for bleaching teeth is an AC-powered device that consists of a light or an electric heater intended to apply heat to a tooth after it is treated with a bleaching agent.

(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.


§ 872.6510 Oral irrigation unit.

(a) Identification. An oral irrigation unit is an AC-powered device intended to provide a pressurized stream of water to remove food particles from between the teeth and promote good periodontal (gum) condition.

(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.


§ 872.6300 Rubber dam and accessories.

(a) Identification. A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting a tooth through a hole in the center. The device includes the rubber dam, rubber dam clamp, rubber dam frame, and forceps for a rubber dam clamp. This classification does not include devices intended for use in preventing transmission of sexually transmitted diseases through oral sex; those devices are classified as condoms in §884.5300 of this chapter.

(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 §872.9.


§ 872.6570 Impression tube.

(a) Identification. An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.

(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.

§ 872.6640 Dental operative unit and accessories.

(a) Identification. A dental operative unit and accessories is an AC-powered device that is intended to supply power to and serve as a base for other dental devices, such as a dental handpiece, a dental operating light, an air or water syringe unit, and oral cavity evacuator, a suction operative unit, and other dental devices and accessories. The device may be attached to a dental chair.

(b) Classification. Class I (general controls). Except for dental operative unit, accessories are exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to §872.9.


§ 872.6650 Massaging pick or tip for oral hygiene.

(a) Identification. A massaging pick or tip for oral hygiene is a rigid, pointed device intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition.

(b) Classification. Class I (general controls).


§ 872.6710 Boiling water sterilizer.

(a) Identification. A boiling water sterilizer is an AC-powered device that consists of a container for boiling water. The device is intended to sterilize dental and surgical instruments by submersion in the boiling water in the container.

(b) Classification. Class I (general controls).

§ 872.6730 Endodontic dry heat sterilizer.

(a) Identification. An endodontic dry heat sterilizer is a device intended to sterilize endodontic and other dental instruments by the application of dry heat. The heat is supplied through glass beads which have been heated by electricity.

(b) Classification. Class III.

(c) Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before April 21, 1997, for any endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976, or that has on or before April 21, 1997, been found to be substantially equivalent to the endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976. Any other endodontic dry heat sterilizer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.


§ 872.6770 Cartridge syringe.

(a) Identification. A cartridge syringe is a device intended to inject anesthetic agents subcutaneously or intramuscularly. The device consists of a metal syringe body into which a disposable, previously filled, glass carpule (a cylindrical cartridge) containing anesthetic is placed. After attaching a needle to the syringe body and actuating the carpule by partially inserting the plunger on the syringe, the device is used to administer an injection to the patient.

(b) Classification. Class II.

§ 872.6855 Manual toothbrush.

(a) Identification. A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(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.


§ 872.6865 Powered toothbrush.

(a) Identification. A powered toothbrush is an AC-powered or battery-powered device that consists of a handle containing a motor that provides mechanical movement to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(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.


§ 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.


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§ 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

Sec. 874.1 Scope.
874.3 Effective dates of requirement for premarket approval.
874.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

874.1050 Audiometer.
874.1060 Acoustic chamber for audiometric testing.
874.1070 Short increment sensitivity index (SISI) adapter.
874.1080 Audiometer calibration set.
874.1090 Auditory impedance tester.
874.1100 Earphone cushion for audiometric testing.
874.1120 Electronic noise generator for audiometric testing.
874.1325 Electrogastrograph.
874.1500 Gustometer.
874.1600 Olfactory test device.
874.1800 Air or water caloric stimulator.
874.1820 Surgical nerve stimulator locator.
874.1925 Toynbee diagnostic tube.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

874.3300 Hearing aid.
874.3305 Wireless air-conduction hearing aid.
874.3310 Hearing aid calibrator and analysis system.
874.3320 Group hearing aid or group auditory trainer.
874.3330 Master hearing aid.
874.3375 Battery-powered artificial larynx.
874.3490 Tinnitus masker.
874.3430 Middle ear mold.
874.3450 Partial ossicular replacement prosthesis.
874.3495 Total ossicular replacement prosthesis.
874.3540 Prosthesis modification instrument for ossicular replacement surgery.
874.3620 Ear, nose, and throat synthetic polymer material.
874.3665 Mandibular implant facial prosthesis.
874.3730 Laryngeal prosthesis (Taub design).
874.3760 Sacculotomy tack (Cody tack).
874.3820 Endolymphatic shunt.
874.3850 Endolymphatic shunt tube with valve.
874.3880 Tympanostomy tube.
874.3900 Nasal dilator.
874.3930 Tympanostomy tube with semipermeable membrane.