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 be considered with data from other diagnostic components.

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

[68 FR 67367, Dec. 2, 2003]

§ 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 silver 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 gold or metals of the platinum group intended to be incorporated into a dental appliance, such as a denture, to help stabilize the appliance in the patient’s mouth.

(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.


§ 872.3140 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.


§ 872.3165 Precision attachment.

(a) Identification. A precision attachment or preformed bar is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use in prosthetic dentistry in conjunction with removable partial dentures. Various forms of the device are intended to connect a lower partial denture with another lower partial denture, to connect an upper partial
§ 872.3200  

denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a crown, or to connect a fixed bridge to a 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.


§ 872.3200  Resin tooth bonding agent.

(a) Identification. A resin tooth bonding agent is a device material, such as methylmethacrylate, intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a filling.

(b) Classification. Class II.

§ 872.3220  Facebow.

(a) Identification. A facebow is a device intended for use in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is intended for use in placing denture casts accurately into an articulator (§872.3150) and thereby aiding correct placement of artificial teeth into a denture base.

(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. 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 §820.196, with respect to complaint files.


§ 872.3240  Dental bur.

(a) Identification. A dental bur is a rotary cutting device made from carbon steel or tungsten carbide intended to cut hard structures in the mouth, such as teeth or bone. It is also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices.

(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.


§ 872.3250  Calcium hydroxide cavity liner.

(a) Identification. A calcium hydroxide cavity liner is a device material intended to be applied to the interior of a prepared cavity of a tooth before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.

(b) Classification. Class II.

§ 872.3260  Cavity varnish.

(a) Identification. Cavity varnish is a device that consists of a compound intended to coat a prepared cavity before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.

(b) Classification. Class II.

§ 872.3275  Dental cement.

(a) Zinc oxide-eugenol—(1) Identification. Zinc oxide-eugenol is a device composed of zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.

(2) 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.

(b) Dental cement other than zinc oxide-eugenol—(1) Identification. Dental cement other than zinc oxide-eugenol is a device composed of various materials other than zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.
§ 872.3285 Preformed clasp.

(a) Identification. A preformed clasp or a preformed wire clasp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be incorporated into a dental appliance, such as a partial denture, to help stabilize the appliance in the patient’s mouth by fastening the appliance to an adjacent 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.

§ 872.3300 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 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.

(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, 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, 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.

§ 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 III. Any other ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 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, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carboxymethylcellulose sodium and cationic polyacrylamide polymer 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 carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976.

§ 872.3430 Ethylene oxide homopolymer and/or ethylene oxide homopolymer and/or karaya denture adhesive.

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

(b) Classification. (i) 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 III. The device is 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 (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.

§872.3480 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. A PMA or a notice of completion of a PDP is required.

(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 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 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
§ 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 subpart E of part 807 of this chapter subject to the limitations in §872.9.

§ 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.”

§ 872.3560 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.”

§ 872.3570 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
§ 872.3580 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.

§ 872.3600 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:

(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]

§ 872.3630 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.)

[69 FR 26304, May 12, 2004]

§ 872.3640 Endosseous dental implant.

(a) Identification. An endosseous dental implant is a prescription 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) Classification. Class II (special controls). The device is classified as class II if it is a blade-form endosseous dental implant. The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry
and material composition are consistent with the intended use;
(ii) Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;
(iii) Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;
(iv) The device must be demonstrated to be biocompatible;
(v) Sterility testing must demonstrate the sterility of the device;
(vi) Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;
(vii) Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, relevant precautions and warnings based on the clinical use of the device, and qualifications and training requirements for device users including technicians and clinicians;
(viii) Patient labeling must contain a description of how the device works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and
(ix) Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

§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.

§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 analog or digital methods for use in the computer-assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software.

(b) Classification. Class II (Special Controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of the chapter subject to the limitations in §872.9. The special control for these devices is the FDA guidance document entitled “Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA.” For the availability of this guidance document, see §872.1(e).

§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.


§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.


§872.3740 Retentive and splinting pin.

(a) Identification. A retentive and splinting pin is a device composed of cast 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.

§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]
§ 872.3750 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 methylmethacrylate, 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.

(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 root canal filling resin described in paragraph (b)(2) of this section 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 root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other root canal filling resin shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 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 II (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.


§ 872.3850 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.


§ 872.3890 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.

§ 872.3900 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.


§ 872.3910 Backing and facing for an artificial tooth.

(a) Identification. A backing and facing for an artificial tooth is a device intended for use in fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.

(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, polyactic 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 premarket approval application (PMA) or notice of product development protocol (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.

[70 FR 21949, Apr. 28, 2005]

§ 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 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.


§ 872.3960 Mandibular condyle prosthesis.

(a) Identification. A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.

(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 mandibular condyle 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 mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 872.3970 Interarticular disc prosthesis (interpositional implant).

(a) Identification. An interarticular disc prosthesis (interpositional implant) is a device that is intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

(b) Classification. Class III.
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§ 872.4475 Spring-powered jet injector.

(a) Identification. A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

(b) Classification. Class II.

Subpart E—Surgical Devices

§ 872.4120 Bone cutting instrument and accessories.

(a) Identification. A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw. The device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw.

(b) Classification. Class II.

§ 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.

(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.

§ 872.4200 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.

§ 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.

§ 872.4475 Spring-powered jet injector.

(a) Identification. A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

(b) Classification. Class II.