§ 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:

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 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:

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]

§ 872.3580 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.


§ 872.3590 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
§ 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.


§ 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).

[68 FR 19738, Apr. 22, 2003]

§ 872.3670 Resin impression tray material.

(a) Identification. Resin impression tray material is a device composed of materials such as methyl methacrylate, and is used to form a custom impression tray. This tray is then filled with impression material 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).