(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:

(i) 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.

[69 FR 26304, May 12, 2004, as amended at 79 FR 34625, June 18, 2014]

§ 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).

[52 FR 30097, Aug. 12, 1987, as amended at 68 FR 19738, Apr. 22, 2003]

§ 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 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.

§ 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