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 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.** 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).

[68 FR 19738, Apr. 22, 2003]