DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 1, 2015

Zimmer Dental Inc.
Ms. Christina Boydston
Regulatory Affairs Manager
1900 Aston Ave.
Carlsbad, California 92008

Re: K143528
Trade/Device Name: Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 2, 2015
Received: April 3, 2015

Dear Ms. Boydston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143528

Device Name: ***Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System***

Indications For Use:

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Engaging, is intended for use in the creation of a customized abutment for a cement-retained crown or bridge, or a customized screw-retained restoration.

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Non-Engaging, is intended for use in the creation of customized multiple-unit restorations on implants (e.g., bars and bridges), when anti-rotation of the abutment is not necessary.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zimmer Dental
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Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR807.92(a))

K143528

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4300
Contact:	Christina Boydston
Date Prepared:	April 29, 2015

2. Device Name:

Trade Name:	Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System
Regulation Number:	872.3630
Classification Code:	NHA
Classification:	II
Device Classification Name:	Abutment, Implant, Dental, Endosseous

3. Predicate Device(s):

Predicate Device No. 1

Trade Name:	"Cast-To" Gold Abutments, Engaging
510(k) Number:	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Predicate Device No. 2

Trade Name:	"Cast-To" Gold Abutments, Non-Engaging
510(k) Number:	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

4. Device Description:

The purpose of an abutment with Cast-to capabilities is to satisfy customer needs of attaching cast framework prostheses to an abutment. The non-engaging Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System can be used as base to cast frameworks for multiple unit crown and bridge and bar over denture restorations by a dental laboratory using a precious metal alloy. The engaging Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System can be used as base to cast a single abutment for a cement-retained crown or bridge and frameworks for multiple unit crown and bridge and bar over denture restorations by a dental laboratory using a precious metal alloy. The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System is designed for use with Zimmer 3.1mmD Dental Implant System to support cast framework prostheses. The engaging abutment/implant interface is an internal conical connection with a hex. The non-engaging abutment/implant interface is a connection that sits on top of the implant but does also has cylindrical features that sit passively within the implant.

The abutment is composed of Gold Alloy 6019 and secured to the implant with a separate Titanium alloy screw for retention.

5. Indications for Use:

Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Engaging

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Engaging, is intended for use in the creation of a customized abutment for a cement-retained crown or bridge, or a customized screw-retained restoration.

Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Non-Engaging

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Non-Engaging, is intended for use in the creation of customized multiple-unit restorations on implants (e.g., bars and bridges), when anti-rotation of the abutment is not necessary.

6. Device Comparison:

Differences in technological characteristics between the subject and predicate device did not raise different questions of safety and effectiveness, and that mechanical testing was used to support a conclusion of substantial equivalence (please see non-clinical testing section for details). The subject abutment is substantially equivalent to the predicate relative to material, general design features as well as design and manufacturing process. It is fabricated from Gold alloy. The differences are the implant/abutment interface and platform sizes. The subject abutment and base device will be affixed to the implant by a retaining screw, the same manner as the predicate.

7. Technological Characteristics

Feature	**Subject Device 1** Zimmer Cast-to Gold Abutment for the 3.1mmD Dental Implant System, Engaging	**Predicate 1** "Cast-To" Gold Abutments, Engaging K011028	**Subject Device 2** Zimmer Cast-to Gold Abutment for the 3.1mmD Dental Implant System, Non-Engaging	**Predicate 2** "Cast-To" Gold Abutments, Non-Engaging K011028
Material	Gold Alloy 6019	Gold Alloy 6019	Gold Alloy 6019	Gold Alloy 6019
Implant Interface	Internal Hex Conical Connection	Internal Hex	Non-engaging conical connection	Non-hex connection that sits on the top of the implant
Platforms	2.9mm	3.5mm, 4.5mm, 5.7mm	2.9mm	3.5mm, 4.5mm
Maximum Abutment Angulation	30°	30°	30°	30°
Method of Attachment	Retaining screw	Retaining Screw	Retaining screw	Retaining Screw
Retaining Screw	Cat. No. CUAS Cat. No. CASLC	Cat. No. MHLAS Cat. No. MTWSD	Cat. No. CUAS	Cat. No. MHLAS

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance of fatigue and compression testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments and ISO 14801:2007 Dentistry — Implants — Dynamic fatigue test for endosseous dental implants. The testing indicates that the subject device is substantially equivalent to the predicate device in terms of static and fatigue testing.

In addition, the Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System will be sold non-sterile and will be sterilized by the end user. The sterilization procedures listed in the Instruction for Use were validated to provide a minimum sterility assurance level of 10^{-6}.

The subject abutment will be manufactured using biocompatible material. The subject abutment will be manufactured using the same material as the predicate which were cleared in K011028; therefore, no additional biocompatibility testing was performed on the subject device. The Biocompatibility of the raw material and manufacturing process testing of Gold Alloy 6019 was previously conducted, documented and cleared in the predicate submission (K011028). Biocompatibility testing was completed in compliance to ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

Additionally, Zimmer Dental implant systems were evaluated for interactions with magnetic fields during Magnetic Resonance Imaging (MRI) in accordance with the FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment and ASTM F 2182: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging. The results of these tests support the MR conditional labeling of this device.

9. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of substantial equivalence.

10. Conclusion

The subject device, Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System are gold alloy, abutments with an engaging or non-engaging interface and are designed to provide support for a cast framework.

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System is equivalent to predicate devices in general abutment design, manufacturing process, material, indications, mechanical performances, and risk. The subject devices are Magnetic Resonance Imaging (MRI) compatible conditionally with respect to patient safety.

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System will be manufactured from the same biocompatible material (Gold Alloy 6019) as predicate devices, will be manufactured and inspected according to approved engineering drawings, and Zimmer Dental procedures, and will be packaged in a similar manner as the predicate devices. The subject devices will be sold non-

sterile and will be labeled as “non-sterile”, and is intended to be sterilized by the end user. The sterilization procedures were validated to provide a minimum sterility assurance level of $10^{-6.}$

Based on the above analysis and the 510(k) submission for Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, the subject device is substantially equivalent to the predicate