DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 25, 2015

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

Re: K143505
Trade/Device Name: Zimmer® Patient Specific Abutment, Internal Hex, Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 25, 2015
Received: March 27, 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): K143505

Device Name: ***Zimmer® Patient Specific Abutment, Internal Hex, Titanium***

Indications For Use:

The Zimmer® Patient Specific Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.

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
1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
760.431.7811 (fax)

PRE-MARKET NOTIFICATION 510(k)

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

K143505

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4300
Contact:	Christina Boydston
Date Prepared:	December 8, 2014

2. Device Name:

Trade Name:	*Zimmer*® Patient Specific Abutment, Internal Hex, Titanium
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

3. Predicate Device(s):

Predicate Device No. 1

Trade Name:	*Zimmer*® Patient Specific Abutment, Internal Hex, Titanium
510(k) Number:	K071439
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Predicate Device No. 2

Trade Name:	Zimmer Zfx Abutment for Nobel Active Implant System
510(k) Number:	K134045
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Predicate Device No. 3

Trade Name:	Zimmer Zfx Titanium Abutment for Biomet 3i Certain Implant System
510(k) Number:	K141544
Regulation Number:	872.3630

Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

4. Device Description:

The *Zimmer*® Patient Specific Abutment, Internal Hex, Titanium is designed for use with internal hex connection implants to support single or multi tooth restorations. The abutment/implant interface is an internal hexagonal connection. The proposed changes to the Zimmer Patient-Specific Abutment include changes to the design parameters with respect to the margin width and radius, the cuff height and the cuff width. The updated design parameters do not affect the device's intended use or alter the fundamental scientific technology of the device.

The *Zimmer*® Patient Specific Abutment, Internal Hex, Titanium is a patient specific dental implant abutment. The purpose of a Patient-Specific abutment is to satisfy patient's needs that are otherwise difficult to meet with off-the-shelf abutments. They can be manufactured in multiple sizes, shapes, and angles within the limits established in this submission. They frequently incorporate the modifications typically done at a dental laboratory or "chair-side" by a dentist. Traditional methodologies require the customer (dentist/laboratory technician) to begin with a "stock" abutment and use manual subtractive techniques to remove material from this original "stock" design. However, a Patient-Specific abutment will incorporate these same modifications desired by the customer (dentist/laboratory technician) at the time of fabrication at the manufacturing facility.

The engineering drawings list ranges in areas (attributes) of the abutment that may be modified depending upon patient-specific needs.

The abutment is composed of Titanium alloy (Ti6Al4V), and secured to the implant with a separate Titanium alloy screw for retention.

The abutment is offered in 3.5mm, 4.5mm, and 5.7mm implant platforms.

5. Indications for Use:

The Zimmer® Patient Specific Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.

6. Device Comparison:

The proposed changes to the *Zimmer*® Patient Specific Abutment, Internal Hex, Titanium include changes to the design parameters with respect to the margin width and radius, the cuff height and the cuff width. The updated design

parameters do not affect the device's intended use or alter the fundamental scientific technology of the device. Further the updated parameters are similar to the parameters called out for the predicate devices. The new abutment does not change relative to the material, manufacturing process or general design features.

The new abutment device is substantially equivalent to the predicate and remains the same as the current device relative to material, manufacturing process and general design features. It is fabricated from Titanium alloy and utilizes an internal hexagonal connection, which is identical in size and shape (for a given platform diameter) to the predicate device and the current device. The new abutment will be affixed to the implant by a retaining screw in the same manner as the predicate.

6. Technological Characteristics

Feature	**New Device** *Zimmer*® Patient Specific Abutment, Internal Hex, Titanium	**Existing Device (K071439)** *Zimmer*® Patient Specific Abutment, Internal Hex, Titanium	**Predicate #2** Zimmer Zfx Titanium Abutment for NobelActive Implant System	**Predicate #3** Zimmer Zfx Titanium Abutment for Biomet 3i Certain Implant System
Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V
Implant Interface	Internal hex, friction-fit	Internal hex, friction-fit	Internal Conical, Internal Hex	Internal Hex
Emergence	Contoured/curved depending on anatomy	Contoured/curved depending on anatomy	Contoured/curved depending on anatomy	Contoured/curved depending on anatomy
Margin	Pre-machined	Pre-machined	Pre-machined	Pre-machined
Platform Diameter	3.5mm, 4.5mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	3.5mm, 3.9mm	3.4mm, 4.1mm, 5.0mm, 6.0mm
Cuff Width	3.5mm Platform: 3.5-9.0 4.5mm Platform: 4.5-10.0 5.7mm Platform: 5.7-12.0	3.5mm-8.0mm	3.5mm Platform: 3.0-9.0 3.9mm Platform: 3.4-9.0	3.4mm Platform: 3.4-8.0 4.1mm Platform: 4.1-9.0 5.0mm Platform: 5.0-10.0 6.0mm Platform: 6.0-12.0
Cuff Height ***(note: screw must be covered)***	No limit	0.5mm-6.0mm	No limit	No limit
Cone Angle	0°-30°	0°-30°	0°-25°	0°-30°
Retaining Screw	MHLAS	MHLAS	ZFX09000627, ZFX09000628	ZFX09000978

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence in K071439. 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. The testing indicates that the new device is strong enough to withstand the anticipated forces and demonstrated improvements over the predicate device(s). This testing was previously reviewed and accepted under K071439.

In addition, the *Zimmer*® Patient Specific Abutment, Internal Hex, Titanium 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}.

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. This was done to determine that the presence of the abutment poses no additional restrictions on MRI beyond those that would otherwise occur for the patient.

9. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of safety and effectiveness.

10. Conclusion

Based on our analysis, the device is substantially equivalent to the predicate and the intended uses have not changed from the previously cleared device submitted under K071439.