Zimmer Dental
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JUL 18 2014

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

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

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4315
Contacts:	Melissa Burbage Kerry Foote
Date Prepared:	June 13, 2014

2. Device Name:

Trade Name:	Zimmer Zfx Titanium Base Abutment
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Implant, Abutment

3. Predicate Device(s):

Predicate Device No. 1

Trade Name:	Hex Lock Abutment
510(k):	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Implant, Abutment

Predicate Device No. 2

Trade Name:	Zimmer Pre-angled Ti Abutment
510(k):	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Implant, Abutment

Predicate Device No. 3

Trade Name:	Strauman® Variobase™ Abutments
510(k):	K132219
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Implant, Abutment

4. Device Description:

The Zimmer Zfx Titanium Base Abutment is a combination of a pre-manufactured (stock) abutment and the Zimmer Zfx Abutment Coping or Crown as part of a two piece abutment. The abutment is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment is used for single unit restorations in the anterior and posterior regions. The abutment base will be made available in 3.5, 4.5 and 5.7mm platforms. The Zimmer Zfx Titanium Base serves as a bonding base that allows for cementation of a patient-specific restoration. Copings, crowns and bridges can be used with the Zimmer Zfx Titanium Base.

The Zimmer Zfx Abutment Coping is a zirconia mesostructure component that would be cemented onto the Zimmer Zfx Titanium Base Abutment to form the two-piece abutment. These componenents will be manufactured from zirconia or IPS e.Max. The maximum angulation that is allowed is 20°. The two piece abutment would then be able to be used as a terminal or intermediate abutment for cement or screw retained prostheses that is for a single or multi-unit (bridge) restoration. The Zimmer Zfx Abutment Coping would require a separate crown to be cemented onto the coping or direct veneering to be applied.

5. Indications for Use:

The Zimmer Zfx Titanium Base Abutment is a combination of a pre-manufactured (stock) abutment and the Zimmer Zfx Abutment Coping or Crown as part of a straight or angled two piece abutment. The combination of the titanium base stock abutment and the abutment coping is designed for use as a terminal or intermediate abutment for cement or screw retained prostheses. The two-piece abutment is used for a single-unit or multi-unit (bridge) restoration. The Zimmer ZFx Abutment Coping shall be manufactured by an approved Zimmer Dental milling facility.

6. Device Comparison:

The new device is substantially equivalent to the predicate device, in that it is manufactured with the same material, has the same intended use, and contains the same abutment/implant interface design. The function in the endosseous implant system remains the same as the predicate devices. The new device is fabricated from Titanium alloy and utilizes the hex implant/abutment interface, which is identical in size and shape (for a given platform diameter) to the predicate device. The new device will be affixed to the implant by a retaining screw. In addition, the new titanium base is similar to that of the predicate device. The new device will be utilized with the same Zimmer Dental Product Lines as the predicate device. The Zimmer Zfx Titanium Base is designed with a shorter and narrower cone, when compared to the predicate device. By minimizing

the size of the cone on the Titanium Base, the amount of metal available to be seen through the final restoration is minimized producing a more aesthetic finish.

7. Technological Characteristics

Feature	New Device Zimmer Zfx Titanium Base Abutment for Zimmer Tapered Screw-Vent Implant System	Predicate 1 Zimmer Hex Lock Abutment 510(k) K011028	Predicate 2 Zimmer Pre-Angled Ti Abutment K011028	Predicate 3 Strauman® Variobase™ Abutments K132219
Indications	The Zimmer Zfx Titanium Base Abutment is a combination of a pre-manufactured (stock) abutment and the Zimmer Zfx Abutment Coping or Crown as part of a straight or angled two piece abutment. The combination of the titanium base stock abutment and the abutment coping is designed for use as a terminal or intermediate abutment for cement or screw retained prostheses. The two-piece abutment is used for a single-unit or multi-unit (bridge) restoration. The Zimmer ZFx Abutment Coping shall be manufactured by an approved Zimmer Dental milling facility.	For use as a terminal abutment for cemented prosthesis. Abutments are for single unit restorations. Single use.	For use as a terminal abutment for cemented prosthesis. Abutments are for single unit restorations. Single use.	Strauman® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Strauman dental implants to provide support for customized prosthetic restorations such as crown and bridges. Strauman® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.
Implant Interface	Internal Hex	Internal, Hex	Internal, Hex	Various
Abutment Platform Diameter	3.5mm, 4.5mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	3.5, 4.5, 5.7 mm	Various
Material	Titanium 6Al-4V (base) Zirconia (coping/crown)	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-7Nb (base) Zirconia/Zerion (coping/crown) Acrylic/polycon (coping/crown)
Packaging	PETG tray	Cap/Vial	Cap/Vial	Not identified
Compatible with CAD/CAM patient-specific restorations	Yes	Yes	Yes	Yes
Compatible with Traditional patient-specific restorations	Yes	Yes	Yes	Yes

8. Non-Clinical Testing:

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.

Additionally, in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments, non-clinical mechanical testing of the Zimmer Zfx Titanium Base Abutment was performed. Two different tests were conducted in order to characterize the mechanical strength of the new device. The first test consisted of the Titanium base portion of the new device assembled in a abutment test setup. A hemispherical test cap, representing a final restoration, was cemented directly to the Titanium base portion of the device. The results demonstrated that the Titanium base portion of the new device is equivalent to the currently marketed Zimmer Hex Lock Abutment (K011028). The second test evaluated the new device as a two-piece abutment system. The testing was performed with the Titanium base portion of the new device and a 20 degree angulated Zirconia mesotructure cemented together. The results demonstrated that the two-piece abutment system is substantially equivalent to the currently marketed Zimmer Pre-Angled Ti Abutment (K011028).

Clinical Testing:

In accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments, clinical testing of the Zimmer Zfx Titanium two piece Abutment was not performed. The device is not significantly different from the predicate device and also contains the same design features, technological characteristics and indications as the currently marketed Zimmer Hex Lock Abutment (K011028).

9. Conclusion:

Based on our analysis, the device is substantially equivalent to the predicate.

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

July 18, 2014

Zimmer Dental, Inc.
Melissa Burbage
Associate Director, Regulatory Affairs
1900 Aston Ave.
Carlsbad, CA 92008

Re: K133551
Trade/Device Name: Zimmer Zfx Titanium Base Abutments for Tapered Screw-Vent Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 16, 2014
Received: June 18, 2014

Dear Ms. Burbage:

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,

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

zimmer dental

Indications for Use

510(k) Number (if known): K133551

Device Name: Zimmer Zfx Titanium Base Abutments for Tapered Screw-Vent Implant System

Indications For Use:

The Zimmer Zfx Titanium Base Abutment is a combination of a pre-manufactured (stock) abutment and the Zimmer Zfx Abutment Coping or Crown as part of a straight or angled two piece abutment. The combination of the titanium base stock abutment and the abutment coping is designed for use as a terminal or intermediate abutment for cement or screw retained prostheses. The two-piece abutment is used for a single-unit or multi-unit (bridge) restoration. The Zimmer ZFx Abutment Coping shall be manufactured by an approved Zimmer Dental milling facility.

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)

Lauren M. Giles -S 2014.07.18 15:58:56 -04'00' for SAG