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

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

NOV 8 2012

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

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4300
Contact:	Melissa Burbage
Date Prepared:	November 1, 2012

2. Device Name:

Trade Name:	Zimmer Zfx Abutment for NobelReplace Implant System
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Dental Implant Abutment

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:	Endosseous Dental Implant Abutment

Predicate Device No. 2

Trade Name:	NobelProcera Ti Abutment
510(k) Number:	K091756
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Dental Implant Abutment

Predicate Device No. 3

Trade Name:	Replace TiUnite Endosseous Implant
510(k) Number:	K023113
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-form

4. Device Description:

The purpose of a Patient-Specific abutment is to satisfy customer needs that are otherwise difficult to meet with off-the-shelf abutments. They can be manufactured in multiple sizes, shapes, and angles. They frequently incorporate the modifications typically done at a dental laboratory or "chair-size" 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, the 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 Zimmer Zfx Abutment for NobelReplace Implant System is a dental implant abutment with a fixed competitor compatible interface. It is designed for use with NobelReplace endosseous dental implants to support single or multi tooth restorations. The abutment-implant interface is an internal tri-lobe. 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 it is secured to the implant with a separate Titanium alloy screw for retention.

The new abutment will be available with a choice of 3.5mm, 4.3mm, 5.0mm, and 6.0mm platform diameters. The maximum abutment angulation will be 20°. The new abutment will interface with Nobel Replace implants with an internal tri-lobe connection.

5. Indications for Use:

The Zimmer Zfx Abutment for Nobel Replace Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with NobelReplace, Replace Select and NobelSpeedy Replace implants with a Narrow Platform (NP) Ø 3.5 mm, Regular Platform (RP) Ø 4.3 mm, Wide Platform (WP) Ø 5.0 mm or 6.0 Platform (6.0) Ø 6.0 mm.

6. Device Comparison:

The new device is substantially equivalent to the predicate relative to material and general design features. The function in the endosseous implant system remains the same as the predicate devices. It is fabricated from Titanium alloy and utilizes the tri-lobe implant/abutment interface, which is similar 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, the same manner as the predicate. Mechanical fatigue testing has demonstrated that all sizes of the implant/abutment assembly are mechanically suitable for placement in all regions of the mouth, including the posterior.

7. Technological Characteristics

Feature	New Device Zimmer Zfx Abutment for NobelReplace Implant System	Predicate 1 Zimmer Titanium PSA	Predicate 2 Nobel Procera Abutment	Predicate 3 NobelReplace NP Abutment
Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium or Titanium 6Al-4V	Titanium or Titanium 6Al-4V
Implant Interface	Internal Tri-lobe	Internal Hex	Internal Tri-lobe	Internal Tri-lobe
Emergence	Contoured, curved	Contoured, curved	Contoured, curved	Contoured, curved
Margin	Pre-machined	Pre-machined	Pre-machined	Pre-machined
Platform Diameter	3.5mm, 4.3mm, 5.0mm, 6.0mm	3.5mm, 4.5mm, 5.7mm	3.5mm, 4.3mm, 5.0mm, 6.0mm	3.5mm
Cuff Width	3.5mm-12mm	3.5mm-8.0mm	3.5mm-16mm	4.2mm
Cone and Overall Cone Height	3.0-11.5 Cone 3.5-12.0 Overall	3mm-12mm	15mm overall abutment height	6.5-7.5mm
Maximum Angulation	20°	30°	25°	15°
Retaining Screw	New device	Cat. No. MHLAS	Cat No 36818 & 29475	Cat No 36818

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence. This consisted of reverse engineering, compatibility analysis and mechanical fatigue testing. The NobelReplace interface was reverse engineered based on actual measurements taken off NobelReplace implants, abutments and retaining screws in order to assure that the Zimmer Zfx Abutment for NobelReplace Implant System is compatible with NobelReplace Implants with tri-lobe connection. Dimensional specifications were developed for the Zimmer fabricated components based on the reverse engineering results. A tolerance analysis as well as a rotational analysis was conducted to illustrate the nature of fit between the Zimmer fabricated parts and the OEM implant. To verify the compatibility of the Zimmer device to the OEM device, fatigue testing was completed using Zimmer fabricated abutments assembled to OEM implants in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments. The results were compared to fatigue testing data of the NobelReplace predicate device and demonstrated that the proposed device is substantially equivalent to the predicate device. Based on the reverse engineering process, as well as verification of the final connection dimensions and tolerances, the

Zimmer Zfx Abutment for NobelReplace Implant System can be deemed compatible with the NobelReplace tri-lobe implant interface.

In addition, the Zimmer Zfx Abutment for Nobel Replace Implant System will be sold non-sterile and will be sterilized by the end user. The sterilization procedures listed in the instructions-for-use were validated to provide a minimum sterility assurance level of 10^{-6}.

9. Clinical Testing

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

10. 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 20993-002

Letter Date: November 8, 2012

Zimmer Dental Incorporated
Ms. Melissa Burbage
Associate Director Regulatory Affairs
1900 Aston Avenue
Carlsbad, California 92008

Re: K120873
Trade/Device Name: Zimmer Zfx Abutment for Nobel Replace Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 1, 2012
Received: November 2, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=13001836 18
Date: 2012.11.08 15:54:26 -05'00'

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120873

Attachment 1

Zimmer

Indications for Use

510(k) Number (if known): K120873

Device Name: ***Zimmer Zfx Abutment for Nobel Replace Implant System***

Indications For Use:

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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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120873