zimmer
dental

Zimmer Dental
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510k No.: K111853

DEC - 8 2011

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: 760-929-4300
Contact: Melissa Burbage

Date Prepared: June 27, 2011

2. Device Name:
Trade Name: Angled Tapered Abutment
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

3. Predicate Device(s):

Predicate Device No. 1
Trade Name: NobelActive Multi Unit Abutment
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

Predicate Device No. 2
Trade Name: Tapered Abutment
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

4. Device Description:

The Angled Tapered Abutment has an external hex which engages the hex of the Tapered Screw-Vent and Screw-Vent implant. The abutments are available in multiple cuff heights and in both 15° and 30° configurations to provide angulation correction for off-angle implant placement. The abutment is secured to the implant with an abutment retaining screw. The abutment screw is preassembled in the abutment

and is not removable from the abutment. The abutment has a tapered cone with an internal screw access for the attachment of various restorative components using a separate coping screw. The abutment cone has a 15° taper and is 1.2mm tall. Abutments are packaged with a metal delivery tool to assist with the placement and orientation of the abutment into the implant. The abutment and abutment retaining screw are fabricated from titanium alloy.

The current tapered abutments facilitate multiple-unit, screw-retained restoration. These abutments do not engage the internal hex connection and are not for use in single-unit. While the current tapered abutments are somewhat limited to straight restoration, the new device will expand the functionality of our screw retained restoration by permitting angled restoration. It will be available in titanium 6Al-4V and will provide an angulation up to 30°.

5. Indications for Use:

The Angled Tapered Abutment is used for a terminal or intermediate abutment for screw-retained multiple-unit restorations. The 30°Angled Tapered Abutment must be used within 45 degree of parallelism for a splinted restoration. The 15°Angled Tapered Abutment must be used within 30 degrees of parallelism for a splinted restoration.

6. Device Comparison:

The Angled Tapered Abutment is substantially equivalent to the predicate NobelActive Multi Unit Abutment in the material, implant/abutment connection, abutment platforms and angulations. The Angled Tapered Abutment is substantially equivalent to the predicate Tapered Abutment in the material, implant/abutment connection, abutment platforms, and mating of prosthetic components.

7. Technological Characteristics

Feature	New Device 1 Angled Tapered Abutment	Predicate No. 1 NobelActive Multi Unit Abutment	Predicate No. 2 Tapered Abutment
Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V
Abutment angles	Up to 30°	Up to 30°	0°
Platforms	3.5, 4.5mm	3.5, 3.9mm	3.5, 4.5, 5.7mm
Method of Attachment	Internal screw threaded through internal hex into implant	Internal screw threaded through internal hex into implant	Internal screw threaded through internal hex into implant

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of safety and effectiveness. 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 device is strong enough to withstand the anticipated forces and demonstrated improvements over the predicate device.

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 considers the new device is as safe and effective for its intended use and performs as well or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC - 8 2011

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

Re: K111853
Trade/Device Name: Angled Tapered Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 14, 2011
Received: December 1, 2011

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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): K111853

Device Name: ***Angled Tapered Abutment***

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)

Susan Runner

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

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