Zimmer Dental
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Carlsbad, CA 92008
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510k No.: K113753

zimmer dental

AUG 30 2012

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: Jeremy Markovich

Date Prepared: December 19, 2011

2. Device Name:

Trade Name: *Tapered Screw-Vent*® X Implant
510(k) Number: K112160
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant

3. Predicate Device(s):

Predicate Device No. 1
Trade Name: Zimmer Dental *Tapered Screw-Vent*® P Implant
510(k) Number: K101880
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant

Predicate Device No. 2
Trade Name: Zimmer Dental *Tapered Screw-Vent*® Implant System
510(k) Number: K011028 / K953101 / K013227 / K061410 / K072589
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant

4. Device Description:

The *Tapered Screw-Vent®* X Implant is an endosseous dental implant. The implant is composed of titanium alloy and Trabecular metal. The implant section is designed for ease of implantation and with greater surface area for osseointegration. The implant section surface is treated to facilitate osseointegration. In addition, the implant section is tapered with triple-lead threads.

The *Tapered Screw-Vent* X implants will be offered in two different texturing configurations: full texture to the top of the implant and texture to 0.5mm from the top of the implant. In addition, both texturing configurations of the implant will have coronal grooves on the collar to within 0.64mm of the top of the implant similar to the predicate *Tapered Screw-Vent®* P Dental implant. The implant/abutment interface platform diameter will be offered in sizes of 3.5mm, 4.5mm, or 5.7mm depending on the outside implant thread diameter. The new device will feature MTX surface equivalent to existing Zimmer Dental implants. The MTX surface is used on the titanium body and is exposed on surfaces apical and coronal to the Trabecular Metal.

5. Indications for Use:

The *Tapered Screw-Vent®* X Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The 4.1mmD *Tapered Screw Vent* X Implants should be splinted to additional implants when used in the posterior region.

6. Device Comparison:

The *Tapered Screw-Vent* X implant is substantially equivalent to Zimmer's *Tapered Screw-Vent* implant. Both implants have the same friction fit internal hexagon connection and use the same prosthetic components to restore the implant. Both implants feature triple lead threads that taper inwardly from the coronal to the apical end of the implant (the overall taper for both of the implants are 2 degrees). Both implants have apical flutes that allow the implant to self tap into the osteotomy. Similar to the *Tapered Screw-Vent®,* the *Tapered Screw-Vent® X* is offered in diameters from 4.1, 4.7, and 6.0mmD (*Tapered Screw-Vent®* is also offered in 3.7mmD) and in lengths 8, 10, 11.5, and 13mmL (*Tapered Screw-Vent®* is also offered in 16mmL).The *Tapered*

Screw-Vent® X and *Tapered Screw-Vent®* all use identical surgical instrumentation and an identical surgical protocol.

7. Technological Characteristics

Feature	Subject Device Tapered Screw-Vent® X	Predicate Device 1 Tapered Screw-Vent® P	Predicate Device 2 Tapered Screw-Vent®
Implant Interface	Internal Hex	Internal Hex	Internal Hex
Implant Lengths	8, 10, 11.5, 13mm	10, 11.5, 13, 16mm	8, 10,11.5, 13, 16mm
Implant Diameters	4.1, 4.7, 6.0mm	4.7, 6.0mm	3.7, 4.1, 4.7, 6.0mm
Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V
Collars	Machined with grooves or texture to top with grooves	Machined with grooves or texture to top with grooves	Machined with grooves or texture to top with grooves
Thread Pattern	Triple lead threads, pattern tightly spaced & equal; partial cylinder type body	Triple lead threads, pattern tightly spaced & equal; partial cylinder type body	Triple lead threads, pattern tightly spaced & equal
Surface Characteristics	MTX Surface and Trabecular Metal ™ (tantalum)	MTX Surface and CSTi™ coating	MTX Surface, or HA Coated, or MP-1® HA Coated

8. Non-clinical Testing

Testing was performed following "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments." Performance testing demonstrated that the device performs appropriately for the proposed indications for use.

9. Clinical Testing

A prospective clinical study was conducted to evaluate the performance of this device within a controlled population that included implantation within the posterior region only and a two week final restoration immediate load protocol with a 6-month end point.

A second, longitudinal data collection study was initiated to gather data on the routine placement and functioning within normal clinical conditions. This population included normal patients and subjects with elevated risk factors that were excluded from the controlled study, such as: alcoholics, substance abusers, mentally unstable, smokers,

osteoporotics, uncontrolled diabetics, parafunctional habits, dental or oral infections, and bone graft patients.

No device related adverse events were reported in either study to date.

10. Conclusion

Based on our analysis, the device is substantially equivalent to the predicates and it is considered that the new device is as safe and effective for its indications for use.

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

AUG 30 2012

Mr. Jeremy Markovich
Seinor Regulatory Affairs Specialist
Zimmer Dental, Incorporated
1900 Aston Ave.
Carlsbad, California 92008

Re: K113753
Trade/Device Name: Tapered Screw-Vent® X Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 24, 2012
Received: August 27, 2012

Dear Mr. Markovich:

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

Tapered Screw-Vent® X Implant

Indications for Use

510(k) Number (if known): K113753

Device Name: *Tapered Screw-Vent® X Implant*

Indications For Use:

The Tapered Screw-Vent® X Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The 4.1mmD Tapered Screw Vent X Implants should be splinted to additional implants when used in the posterior region.

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: K113753