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

510k No.: K111889



DEC - 6 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: July 11, 2011

2. Device Name:
Trade Name: *Tapered Screw-Vent® M* Implant
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant

2. Predicate Device(s):

Predicate Device No. 1
Trade Name: *Tapered Screw-Vent® T* Implant
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant

Predicate Device No. 2
Trade Name: *Tapered Screw-Vent®* Implant System
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant

4. Device Description:

The *Tapered Screw-Vent® M* Implant is an endosseous dental implant. The implant is composed of titanium alloy. 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. The implant contains a 1mm machined collar and small grooves to the top of the implant. In addition, the implant section is tapered with triple-lead threads.

5. Indications for Use:

The *Tapered Screw-Vent® M* 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.

6. Device Comparison:

The *Tapered Screw-Vent® M* Implant is the same as the predicate *Tapered Screw-Vent® T* Implant and *Tapered Screw-Vent®* Implant in the implant/abutment connection, implant body design, materials, and manufacturing. This device has been modified to add the machined collar to the top of the implant similar to the predicate *Tapered Screw-Vent* implant (K061410) and add small grooves on the implant collar identical to the predicate *Tapered Screw-Vent® T* implant. The new device will feature MTX surface equivalent to existing Zimmer Dental implants. The new implant will be offered in 3.7mm, 4.1mm, 4.7mm and 6.0mm diameters.

7. Technological Characteristics

| Feature | **New Device 1** Tapered Screw-Vent® M | **Predicate Device 1** Tapered Screw-Vent® T | **Predicate Device 2** Tapered Screw-Vent® |
|---|---|---|---|
| Implant Interface | Internal Hex | Internal Hex | Internal Hex |
| Implant Lengths | 8, 10, 11.5, 13, 16mm | 8, 10, 11.5, 13, 16mm | 8, 10, 11.5, 13, 16mm |
| Implant Diameters | 3.7, 4.1, 4.7, 6.0mm | 3.7, 4.1, 4.7, 6.0mm | 3.7, 4.1, 4.7, 6.0mm |
| Material | Titanium 6Al-4V | Titanium 6Al-4V | Titanium 6Al-4V |
| Collars | Machined surface and texture, with grooves | Texture to top with grooves | Machined surface and texture |
| Thread Pattern | Triple lead threads, pattern tightly spaced & equal | Triple lead threads, pattern tightly spaced & equal | Triple lead threads, pattern tightly spaced & equal |
| Surface Characteristics | MTX Surface | MTX Surface | MTX Surface |

8. Non-Clinical Testing:

The *Tapered Screw-Vent M* is mechanically similar to the predicate *Tapered Screw-Vent* implant; both implants have the same internal hexagon interface, triple lead threads of the same size and depth, and the same diameter internal thread. Both are fabricated from the same material.

Both the predicate, *Tapered Screw-Vent T,* and the new device, *Tapered Screw-Vent M,* utilize the same lower level drawing for the machined component which was submitted in K101977. They are both made of titanium alloy with the same mechanical properties. Both implants have the same MTX grit blasted surface, with the exception of the 0.5mm wide machined collar finish on the *Tapered Screw-Vent M* implant. Therefore, the *Tapered Screw-Vent M* is mechanically equivalent to the predicate design and mechanical testing is not necessary.

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 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

Ms. Melissa Burbage
Manager, Regulatory Affairs
Zimmer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

DEC - 6 2011

Re: K111889
Trade/Device Name: Tapered Screw-Vent® M Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 17, 2011
Received: October 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,

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): K111889

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

Indications For Use:

The Tapered Screw-Vent® M 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.

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: K111889