



Zimmer Dental  
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Carlsbad, CA 92008  
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510k No.: K092463  
Page No.: A5-1

**Traditional 510(k)  
PRE-MARKET NOTIFICATION 510(k)  
510(k) SUMMARY (21CFR807.92(a))**

**OCT 30 2009**

**1. Submitter's Information:**

Name: Zimmer Dental Inc.  
Address: 1900 Aston Ave.  
Carlsbad, CA 92008  
Phone: 760-929-4300  
Contact: Larissa D'Andrea McMullin  
Date Prepared: October 23, 2009

**2. Device Name: Ti Prepable Abutment  
(cat no. 1618, 1619, 1620)**

Device Classification Name: Endosseous Dental Implant

**3. Predicate Device(s): Integral VII 3.25mm Biointegrated Dental Implant System  
(Fixed Abutment)  
(1506, 1507, 1508, and 1510)**

**4. Device Description:**

The Prepable Abutment is a titanium alloy post with an unprepared shape that allows for preparation by the end user. The spline lines on the inside of the abutment provide an anti-rotation feature and the abutment is secured with a separate retaining screw.

**5. Intended Use:**

The Ti Prepable Abutments are designed for use as a terminal or intermediate abutment for cement retained prostheses. It allows for preparation for the crown to be attached. It can be used for a single or multiple-unit restoration. The abutment is intended to be prepared and placed with patient specific margins.

6. Device Comparison:

The new device is substantially equivalent to the predicate. The devices, general structure, and function in the endosseous implant system remains the same as the predicate devices. It is fabricated from the same titanium alloy as the predicates and utilizes a Spline 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, the same manner as the predicate; however, the retaining screw utilized is different than that used by the predicate. Mechanical fatigue testing has demonstrated that the change in retaining screw does not adversely affect the mechanical strength of the implant/abutment assembly.

Typically abutments are prepared for use by the clinician or a dental laboratory by removing material from the cone and margin areas. The new abutment differs from the predicate by providing more material that the dental clinician or a dental laboratory can utilize to create a natural prosthetic attachment.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Ms. Larissa D'Andrea McMullin  
Associate Manager, Regulatory Affairs  
Zimmer Dental Incorporated  
1900 Aston Avenue  
Carlsbad, California 92008

OCT 30 2009

Re: K092403  
Trade/Device Name: Ti Prepable Abutment  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: July 1, 2009  
Received: August 6, 2009

Dear Ms. McMullin:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", followed by the word "For" in a cursive script.

Susan Runner, D.D.S., M.A.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K092403

Device Name: *Ti Prepable Abutment*

#### Indications For Use:

The Ti Prepable Abutments are designed for use as a terminal or intermediate abutment for cement retained prostheses. It allows for preparation for the crown to be attached. It can be used for a single or multiple-unit restoration. The abutment is intended to be prepared and placed with patient specific margins.

Prescription Use **X**  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Kevin Mulvey for HSR*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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