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

510k No.: K062281

SEP - 5 2006

Special 510(k): Device Modification
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:	Erin L. McVey
Date Prepared:	August 3, 2006

2. Device Name: *Zimmer*® One-Piece Implant, 4.7mm, Straight

   Device Classification Name: Endosseous Dental Implant

3. Predicate Device(s): *Zimmer*® One-Piece Implant, 3.0mm, Straight (cat. no. ZOP30S13)
   Zimmer® One-Piece Implant, 3.7mm, Straight (cat. no. ZOP37S13)

4. Device Description:

   The *Zimmer* One-Piece Implant, 4.7mm, Straight is a one-piece endosseous dental implant which is a combination of implant and abutment sections. The implant is composed of titanium alloy. The abutment portion is pre-prepared and contoured for esthetic restoration. The abutment portion of the implant features a pre-prepared margin to facilitate the restoration process. 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 double-lead threads.

5. Intended Use:

   Zimmer® One-Piece 4.7mm, Straight implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. *Zimmer* One-Piece 4.7mm, Straight implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The *Zimmer*® One-Piece 4.7mm, Straight implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Zimmer® One-Piece, 4.7mm, Straight; 510(k) Summary cont'd:

6. Device Comparison:

The *Zimmer*® One-Piece, 4.7mm, Straight implant is substantially equivalent to the *Zimmer*® One-Piece 3.0mm & 3.7mm, Straight implants as evidenced in mechanical testing. The *Zimmer*® One-Piece Implant, 4.7mm, Straight is substantially equivalent to the *Zimmer*® One-Piece, 3.0mm & 3.7mm, Straight implants in that it is manufactured from one piece of titanium with the abutment and implant portions combined. The new device is a dimensional modification. The materials, general structure, and function in the endosseous implant system remains the same as the 3.0 & 3.7mm, straight one-piece predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Ms. Erin McVey
Senior Regulatory Affairs Specialist
Zimmer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K062281
Trade/Device Name: Zimmer® One Piece Implant, 4.7mm, Straight
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 4, 2006
Received: August 7, 2006

Dear Ms. McVey:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Chiu Lin, Ph.D.
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): K062281

Device Name: *Zimmer*® One-Piece Implant, 4.7mm, Straight

Indications For Use:

Zimmer® One-Piece 4.7mm, Straight implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. *Zimmer*® One-Piece 4.7mm, Straight implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The *Zimmer*® One-Piece 4.7mm, Straight implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

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

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