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

510k No.: K061847

zimmer dental

510(k) SUMMARY (21CFR807.92(a))

OCT 12 2006

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: June 29, 2006

2. Device Name: Zimmer® Contour Ceramic Abutment

   Device Classification Name: Endosseous Dental Implant Abutment

3. Predicate Device(s):

   - ASTRATech ZirDesign™ Ceramic Abutment (Cat. No. 24183)
   - *Zimmer*® Hex-Lock Abutment (Cat. No. HLA3/3)

4. Device Description:

   The Zimmer® Contour Ceramic Abutment is an abutment designed for use with endosseous dental implants to support single or multi tooth restorations. The abutment has a contoured emergence profile to create a more esthetic restoration. The abutment features a pre-machined margin to facilitate the restoration process. The abutment portion is composed of zirconia ceramic with a titanium alloy seating ring and separate titanium alloy screw for retention.

5. Intended Use:

   The Zimmer® Contour Ceramic Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit implant-supported restoration. The 3.5mm abutment is used in the anterior, cuspid, and premolar regions. The 4.5mm abutment can be used in any region of the mouth.

6. Device Comparison:

   Zimmer Dental Inc. believes the Zimmer® Contour Ceramic Abutment to be substantially equivalent to the predicates. They are equivalent in intended use, design, mechanical strength, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2006

Mr. William Fisher
Zimmer Dental, Incorporated
Regulatory Affairs Associate
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K061847
Trade/Device Name: Zimmer® Contour Ceramic Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 2, 2006
Received: October 3, 2006

Dear Mr. Fisher:

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 (301) 443-6597 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): K061847

Device Name: Zimmer® Contour Ceramic Abutment

Indications For Use:

The Zimmer® Contour Ceramic Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit implant-supported restoration. The 3.5mm abutment is used in the anterior, cuspid, and premolar regions. The 4.5mm abutment can be used in any region of the mouth.

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: K061847