K060880

Special 510(k): Device Modification
PRE-MARKET NOTIFICATION 510(k)

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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: William Fisher
Date Prepared: March 29, 2006

2. Device Name: Zimmer Dental Tapered Abutment

   Device Classification Name: Endosseous Dental Implant Abutment

3. Predicate Device: Zimmer Dental 3.5mm Hex-Lock Abutment (cat. No. HLA3/3)
   Zimmer Dental Tapered Abutment (cat. No. TAC2)

4. Device Description:

   The Tapered Abutment is a titanium alloy post with a tapered cone. The abutments are utilized in multi unit configurations with a screw retained bridge threaded directly into them. The new Abutment features a .75mm cuff height.

5. Intended Use:

   The Zimmer Dental Tapered Abutmen is used for screw retained dentures, screw-retained partial dentures and bar Overdenture restorations.

6. Device Comparison:

   The new Tapered abutments and the predicate Tapered abutment have an identical intended use and design with the only difference being the height of the cuff (.75mm vs. 2.0mm). The new Tapered abutment differs from the predicate Hex-Lock abutment by being intended for use in multiple unit screw retained restorations, whereas the predicate device may also be used as a single unit restoration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

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

Re: K060880
Trade/Device Name: Zimmer Dental Tapered Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 26, 2006
Received: April 27, 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): K060880

Device Name: Zimmer Dental Tapered Abutment

Indications For Use:

The Zimmer Dental One Piece Tapered Abutment is intended for use in multiple unit screw retained restorations.

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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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