zimmer dental

Zimmer Dental
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510k No.: K052600

OCT 13 2005

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:	September 19, 2005

2. Device Name*: Zimmer Dental Prepared Hex-Lock Straight Abutment
Zimmer Dental Prepared Hex-Lock Angled Abutment

** Device trade name not available at time of submission.*

Device Classification Name: Endosseous Dental Implant Abutment

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

4. Device Description:

The 'Prepared' Abutment is a titanium alloy post with a tapered cone, predefined margin and varying cuff heights. The abutment engages the internal hex of the implant and is secured with a separate retaining screw. The cone of the abutment is 5.5mm in height, with 8° of taper (4° per side). The height of the cuff is lower on the buccal aspect, higher on the lingual. A vertical groove is located on the lingual aspect of the cone.

The 'Prepared' Angled Abutment is a titanium alloy post with the cone offset by 17°, a predefined margin and varying cuff heights. The abutment engages the internal hex of the implant and is secured with a separate retaining screw. The cone of the abutment is 5.5mm in height, with 8° of taper (4° per side). The height of the cuff is lower on the buccal aspect, higher on the lingual. A vertical groove is located on the lingual aspect of the cone.

5. Intended Use:

The Zimmer Dental Hex-Lock Prepared Abutment, Straight is used as a terminal or intermediate abutment for a cemented prosthesis. The Zimmer Dental Hex-Lock Prepared Abutment, Angled is used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Either abutment can be used for a single or multiple-unit restoration.

6. Device Comparison:

The new straight & angled abutments and the predicate abutment have an identical internal hex friction-fit implant interface. The new device will be affixed to the implant in the same manner as the predicate. The new straight abutment will use the same screw as the predicate. The device modification is a dimensional change. The materials, general structure, and function in the endosseous implant system remains the same as the predicate device.

The new abutment differs from the predicate by providing a prepared margin and cone shape. The end user can make additional modifications if desired, but the new abutment can be used "as is." The taper on the cone of the new abutment is 4 degrees. The new abutment also adds two coronal grooves for crown retention. The cone of the new abutment has a non-circular cross section for anti-rotation compared to a flat side on the predicate design. A vertical groove has been added on the lingual aspect for additional anti-rotation. This feature was added to create better interaction with mating plastic caps. The shape of the emergence profile on the new abutment varies from the predicate. The new abutment has a contoured cuff that rises from the implant platform and flares out to a wider emergence profile diameter.

The predicate is an un-prepared abutment that the dental lab contours specifically for the patient's needs. The predicate abutment has no predefined margin or cone shape. The end user grinds the titanium to define the desired margin and determine the cone geometry. The predicate abutment features straight walls. The end user defines the angle of the cone in their preparation. The predicate's circular grooves are height markings at 1mm intervals to aid in marking the abutment for preparation. The grooves on the predicate are typically removed in the preparation process and are not designed for crown retention. In addition, the predicate design rises straight off the implant platform with no flare.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2005

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

Re: K052600
Trade/Device Name: ZIMMER DENTAL HEX-LOCK PREPARED ABUTMENT (STRAIGHT & ANGLED)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 20, 2005
Received: September 21, 2005

Dear Ms. McVey:

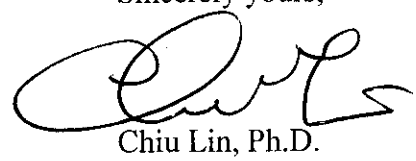
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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

K052600

Indications for Use

510(k) Number (if known): K052600

Device Name: Zimmer Dental Hex-Lock Prepared Abutment (straight & angled)

Indications For Use:

The Zimmer Dental Hex-Lock Prepared Straight Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The Zimmer Dental Hex-Lock Prepared Angled Abutment is used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Either abutment can be used for a single or multiple-unit restoration.

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

510(k) Number: K052600