Zimmer Dental
1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
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510k No.:_____

K090723

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

APR – 7 2009

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 4, 2009

2. Device Name: Hex-Lock Short Abutment,
Short Healing Cap,
Short Provisional Coping
(cat no. SA341, SA342, SA451, SA452, SA561, SA562, SAHEAL4, SAHEAL5, SAHEAL6, SAPROV4, SAPROV5, SAPROV6)

Device Classification Name: Endosseous Dental Implant Abutment

3. Predicate Device(s): Zimmer® Dental 3.5mm Hex-Lock Abutment (HLA3/3)
Zimmer® Contour Healing Cap (e.g.: ZOCHEAL4S)
Zimmer® Contour Provisional Coping (e.g: ZOCPROV4S)

4. Device Description:

The new abutments have a prepared margin and cone shape. A prepared margin and cone shape top portion and an apex with a hex configuration with 1 degree tapered flats. . The taper on the cone of the abutment is 3 degrees. The cone of the abutment has a flat section for anti-rotation.

The Healing Cap is made to precisely fit the abutment for placement on the Abutment at the time of placement to protect the soft tissue during the healing process.

The provisional coping is made to precisely fit the abutments to allow for the placement of a provision crown on the abutment.

5. Intended Use:

The Hex-Lock Short Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. It can be used for a single or multiple-unit restoration.

The Short Healing Cap is for use with a Short Hex-Lock Abutment to prevent irritation of soft tissue due to rubbing against the restorative area of the abutment or implant, and to prevent material from lodging in any undercuts or openings.

The Short Provisional Coping is used for fabricating a cement-retained provisional restoration for a Short Hex-Lock Abutment. Use of the provisional cap is not to exceed 28 days.

6. Device Comparison:

The new devices are equivalent in design with Predicates. The new devices are dimensional modifications to the Predicates cleared in K953101 and K061043. They differs from the Predicate in that they are shorter in overall height. The materials, general structure, and function in the endosseous implant system remains the same as the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR - 7 2009

Re: K090723
Trade/Device Name: Hex-Lock Short Abutment, Short Healing Cap, Short Provisional Coping
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 4, 2009
Received: March 9, 2009

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Sheila A Murphy MD for Susan Runner DDS

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090723

Zimmer Dental Inc. 510(k) No. _____ Attachment 12.13
Hex-Lock Short Abutment 1 of 1

ZIMMER dental

Indications for Use

510(k) Number (if known): _____

Device Name: Hex-Lock Short Abutment,
Short Healing Cap,
Short Provisional Coping

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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)

Kei Maley for MCR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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