Zimmer Dental
1900 Aston Avenue
Carlsbad, CA 92008
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510k No.: K092377

NOV - 3 2009

Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR 807.92(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:	November 3, 2009

2. Device Name: Plastic Temporary Abutment
Device Classification Name: Endosseous Dental Implant Abutment
Device Regulation Number : 872.3630
Product Code : NHA, Dental

3. Predicate Device(s): Hex-Lock® Temporary Abutment
Friadent® EsthetiCap
PreFormance Post

4. Device Description:

The Plastic Temporary Abutments are endosseous dental implant abutments that are designed for single use as a temporary prosthesis during the healing process while the permanent prosthesis is fabricated. The PEEK CLASSIX material, when utilized as a Temporary Abutment, can be placed in use for up to 180 days. They are available in straight and angled versions, with interfaces to match the three diameters of Tapered Screw-Vent Implants, and 1mm or 4mm cuff height options.

5. Indications for Use:

The Plastic Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Plastic Temporary Abutment can be used for cement-retained or screw-retained provisional restoration. The

abutments can be used for single-unit and multi-unit restorations. Use of the Plastic Temporary Abutment is not to exceed one-hundred and eighty (180) days.

6. Device Comparison:

The Plastic Temporary Abutment is substantially equivalent to the original Hex-Lock® Temporary Abutment by design. They are substantially equivalent to the Friadent® EsthetiCap in that the materials and intended use are similar for both products. The Plastic Temporary Abutment is substantially equivalent to the PreFormance Post in that the body of the products are the same material as well as the intended use and period of use are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

NOV - 3 2009

Re: K092377
Trade/Device Name: Plastic Temporary Abutment
Regulation Number: 21CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 3, 2009
Received: August 5, 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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): _____

Device Name: *Plastic Temporary Abutment*

Indications For Use:

The Plastic Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Plastic Temporary Abutment can be used for cement-retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Plastic Temporary Abutment is not to exceed one-hundred and eighty (180) days.

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)

Kevin Mulloy for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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