K072642

BIOMET 3i

510(k) SUMMARY

BIOMET *3i* Dental Abutments & Restorative Components

Submitter	**BIOMET *3i* , Inc.** **4555 Riverside** **Palm Beach Gardens, FL 33410**
Contact	**Diana Taylor** **Manager, Regulatory Affairs** **BIOMET *3i* , Inc.** **4555 Riverside** **Palm Beach Gardens, FL 33410** **Tel. 561-776-6857** **Fax 561-776-6852**
Date Prepared:	**September 14, 2007**
Name of Device:	**BIOMET *3i* Dental Abutments**
Common or Usual Name	**Dental Abutment**
Classification Name	**Abutment, implant, dental, endosseous**
Classification	**Class II** **21 CFR 872.3630**
Product Code	**NHA**
Predicate Devices	**UCLA** **Gingehue** **Certain Provide** **Pre-Angled Abutments** **Conical Abutments** **Tapered Abutments** **Temporary Healing Abutments** **Abutment Posts** **Rocket II Abutments** **IOL Abutments**

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K072642

Intended Use / Indications for Use

BIOMET *3i* Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained to the abutment.

Restorative Components:

- Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing.
- Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics.
- Screw componenets are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.

Technological Characteristics

The BIOMET *3i* dental pre-formed and castable abutments and other restorative components consists of a variety of abutments, posts, cylinders and screws which are utilized to support the single and multiple tooth prostheses for either screw retained or cement retained restoration. These devices include appropriate features and dimensions to mate with BIOMET *3i* dental implants cleared by K063341 and K063286 with either internal or external connections. The abutments may be used for single and multiple teeth.

Substantial Equivalence

The modified BIOMET *3i* dental abutments and restorative components are equivalent to the predicate BIOMET *3i* dental abutments and restorative components having the same intended uses, indications, technological characteristics, and principles of operation as the predicate device(s). The minor technological differences between the modified components and their predicate devices raise no new issues of safety or effectiveness. Thus, the modified dental abutments are substantially equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Ms. Diana Taylor
Manager, Regulatory Affairs
BIOMET 3i, Incorporated
4555 Riverside Road
Palm Beach Gardens, Florida 33410

Re: K072642
Trade/Device Name: BIOMET 3i Dental Abutments and Restorative Components
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 3, 2007
Received: December 5, 2007

Dear Ms. Taylor:

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.

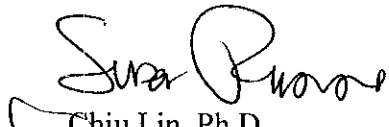
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

K072642

BIOMET 3i

Indications for Use

510(k) Number (if known): _____

Device Name: BIOMET *3i* Dental Abutments and Restorative Components

Indications for Use:

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- Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.

[IDENTIFY WHETHER THE DEVICE IS INTENDED FOR PRESCRIPTION USE AND/OR OVER-THE-COUNTER USE.]

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use __
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sharon Snoddy

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