K073345

MAR - 7 2008

BIOMET 3i

510(k) SUMMARY

BIOMET *3i* Contoured Margin Ceramic Abutment

Submitter:	BIOMET *3i*, Inc. 4555 Riverside Dr Palm Beach Gardens, FL 33410
Contact Person:	Priscilla Caro Regulatory Affairs Specialist BIOMET *3i*, Inc. Riverside Dr Palm Beach Gardens, FL 33410 Tel. 561-776-6785 Fax 561-514-6316
Date Prepared:	November 27, 2007
Name of Device	Certain® Contoured Margin Ceramic Abutment
Trade/Proprietary Name: **Common/Usual Name**	Not available
Classification Name	Abutment, implant, dental, endosseous
Classification	Class II 21CFR 872.3630
Product Code	NHA
Predicate Devices	BIOMET *3i* Dental Ceramic Abutment Zimmer® Contour Ceramic Abutment

Intended Use / Indications for Use

BIOMET *3i* Certain® Contoured Margin Ceramic Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. The Certain® Contoured Margin Ceramic Abutments are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis is cement retained to the abutment.

Technological Characteristics

The BIOMET *3i* Certain® Contoured Margin Ceramic Abutment design consists of different abutments sizes, titanium insert and an abutment screw. These devices included appropriate features and dimensions to mate with BIOMET *3i* Dental Certain® Implant System cleared by K063341 with internal connections.

Substantial Equivalence

The BIOMET *3i* Certain® Contoured Margin Ceramic Abutments substantially equivalent to the predicate BIOMET *3i* Dental Ceramic Abutments and Zimmer® Contour Ceramic Abutment having the same general intended uses, indications, technological characteristics, and principles of operation as the predicate device(s). The minor technological differences between the proposed devices components and their predicate devices raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2008

Ms. Priscilla Caro
Regulatory Affairs Specialist
Biomet 3i, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K073345
Trade/Device Name: Certain® Contoured Margin Ceramic Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 29, 2008
Received: March 3, 2008

Dear Ms. Caro:

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.

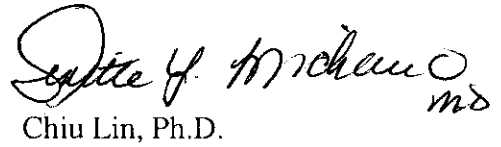
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

BIOMET 3i

Indications for Use

510(k) Number (if known): _____

Device Name: Certain® Contoured Margin Ceramic Abutment

Indications for Use:

BIOMET *3i* Certain® Contoured Margin Ceramic Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. The Certain® Contoured Margin Ceramic Abutments are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis is cement retained to the abutment.

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

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR 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)

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

510(k) Number: K072345