K092341

BIOMET 3i

510(k) Summary

NOV 30 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	BIOMET *3i* 4555 Riverside Drive Palm Beach Gardens, FL 33410
Establishment Registration Number:	1038806
Contact:	Jose E. Cabrera Sr. Manager, Regulatory Affairs BIOMET *3i* 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel. 561-776-6923 Fax. 561-514 6316 Email jose.cabrera@biomet.com
Date Prepared:	July 27th, 2009
Trade/Proprietary Name:	N/A
Common/Usual Name:	Low Profile Abutment
Classification Name:	Abutment, implant, dental, endosseous
Device Classification/Code:	Class II - 21 CFR §872.3630 / NHA
Predicate Device:	Conical Abutments (Straight and Angled), Immediate Occlusal Loading (IOL) Abutments, Asyst Abutment Delivery Device
Indications for Use:	BIOMET *3i* Low Profile 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 is screw retained to the abutment.

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. Jose E. Cabrera
Senior Medical, Regulatory Affairs
Biomet 3*i*, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

NOV 30 2009

Re: K092341
Trade/Device Name: Low Profile Abutment
Regulation Number: 21CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 17, 2009
Received: November 18, 2009

Dear Mr. Cabrera:

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,

for

Susan Runner, D.D.S., M.A.
Acting Division 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: Low Profile Abutment

Indications for Use:

BIOMET *3i* Low Profile Abutments are intended for use as accessories to endosseous dental implants 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 is screw retained to the abutment.

Prescription Use **X** (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)

RSBeck DDS for Dr. Kevin Mulroy

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K042341