K101582

510(k) SUMMARY

NOV - 8 2010

BIOMET 3i – CAM StructSURE Overdenture Bars

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

Submitter:	BIOMET *3i*
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Establishment Registration Number:	1038806
Contact Person:	Jose E. Cabrera
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Date Prepared:	June 3, 2010
Trade/Proprietary Name:	CAM StructSURE Precision Milled Bars
Common/Usual Name:	Overdenture Bars
Classification Name:	Endosseous Dental Abutments
Device Classification:	872.3630
Predicate Device(s) :	BIOMET 3i - PSR Overdenture Bar BIOMET 3i - CAM StructSURE Overdenture Bars Product Codes: CSDXX CSPXX CSHXX CSHYXX CSCMXX
Device Description:	All CAM StructSURE® Precision Milled Bars (Dolder, Primary, Hader, Hybrid and Copy Milled) are designed to match an individual patient. The

	bars are designed from a three-dimensional optical and/or digital scanner system that scans the casting of a patient's impression and then machined using a CAD/CAM software system. The bars are milled from either titanium alloy or CP titanium.
Purpose of Special 510(k):	BIOMET *3i* Patient-Specific CAM StructSURE® Precision Milled Bars are currently scanned and designed with CAD/CAM Delcam and 3Shape scanners and software – BIOMET 3i intends to use Renishaw's scanning, design and milling system which is compatible with currently cleared BIOMET *3i* Patient-Specific CAM StructSURE® Precision Milled Bars.
Intended Use:	The *3i* Patient-Specific CAM StructSURE® Precision Milled Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient.
Nonclinical Performance Data:	Validation performed on scanning equipment and software to ensure accuracy of scanning 3D models and performed Install Qualification.
Clinical Data:	N/A
Substantial Equivalence:	The BIOMET *3i* Patient-Specific CAM StructSURE Overdenture Bars have the same intended use and indications, principles of operation, and technological characteristics as BIOMET *3i* Patient-Specific CAM StructSURE Overdenture Bars. The difference in scanning and milling do not raise any new questions of safety or effectiveness. Validation data demonstrates that the modified process results in a finished device that is as safe and effective as BIOMET *3i* 's Patient-Specific CAM StructSURE Overdenture Bars that are currently cleared with previous scanner systems. Thus, the BIOMET *3i* Patient-Specific CAM StructSURE Overdenture Bars are substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jose E. Cabrera
Senior Manager, Regulatory Affairs
BIOMET 3i, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

NOV - 8 2010

Re: K101582
Trade/Device Name: BIOMET 3i Patient Specific CAM StructSURE Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 14, 2010
Received: October 15, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Anthony D. Watson, B.S., M.S., M.B.A.
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): _____ NOV - 8 2010

Device Name: BIOMET *3i* Patient Specific CAM StructSURE Bars

Indications for Use:

The ***3i*** Patient-Specific CAM StructSURE Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient.

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 OF NEEDED)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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