K080864

JUL 21 2008

Summary of Safety & Effectiveness

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:	Tamara J. West International Regulatory Affairs Manager BIOMET *3i* 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel. 561-776-6923 Fax. 561-514 6316 Email twest@3implant.com
Date Prepared:	March 27, 2008
Trade/Proprietary Name:	CAM StructSURE® Precision Milled Bars
Common/Usual Name:	Overdenture Bar
Classification Name:	Endosseous dental implant abutment 21 CFR § 872.3630
Device Classification:	Class II Dental Devices Panel
Legally Marketed Predicate Devices:	K034035 3i Patient Specific Overdenture Bars

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 is machined using a CADCAM software system. The bars are milled from titanium alloy or CP titanium.

CAM StructSURE® Precision Milled Bars:

- CSHxx CAM StructSURE Hader Bar: 2-10 implants
- CSPxx CAM StructSURE Primary Bar: 2-10 implants
- CSDxx CAM StructSURE Dolder Bar: 2-10 implants
- CSCMxx CAM StructSURE Copy Milled Bar: 4-10 implants
- CSHYxx CAM StructSURE Hybrid Bar: 4-10 implants

Indications for Use:

The CAM StructSURE® Precision Milled Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.

Conclusion:

The proposed design modifications for the CAM StructSURE® Precision Milled Bars were completed under Quality System Design Controls in accordance with 21 CFR 820.30.

Appropriate verification and validation activities were performed to provide assurance that CAM StructSURE® Precision Milled Bars remain substantially equivalent to the predicate and the modifications have not changed the intended use, altered the fundamental scientific technology or the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2008

Ms. Tamara West
International Regulatory Affairs Manager
BIOMET, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K080864
Trade/Device Name: CAM StructSURE® Precision Milled Bars
~~Regulation Number~~: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 6, 2008
Received: May 19, 2008

Dear Ms. West:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): K080864

Device Name: CAM StructSURE® Precision Milled Bars

Indications for Use:

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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)

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

510(k) Number: K080864