MAR 1 1 2011

## K101608 - 510(k) Summary

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

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|---|---|
| **Submitter:** | BIOMET *3i*<br>4555 Riverside Drive<br>Palm Beach Gardens, FL 33410 |
| **Establishment Reg. Number:** | 1038806 |
| **Contact Person:** | Juliana Arias, Regulatory Affairs Specialist |
| **Contact Phone/Fax/Email:** | Tel. 561-776-6999 ext.7208<br>Fax. 561-514-6316<br>Email: *Juliana.Arias@biomet.com* |
| **Date Prepared:** | September 28th, 2010 |
| **Trade/Proprietary Name:** | Encode® Patient Specific Dental Abutments |
| **Common/Usual Name:** | Dental Abutment |
| **Classification Name:** | Root-form Endosseous Dental Abutment |
| **Device Classification/Code:** | 872.3630 |
| **Predicate Device(s) :** | BIOMET *3i* – Encode® Patient Specific Dental Abutments *K032263 & K052648* |
| **Device Description:** | Encode® Patient Specific Dental Abutments are designed specifically for a patient using a CAD/CAM system. The abutments are designed from a three-dimensional intra-oral optical scan or resin model scan and then machined/milled according to the parameters created in a digital file which are derived from the scan. The abutments are manufactured from titanium alloy (Ti 6Al-4V ELI) or biocompatible Zirconia TZP. The abutment design is limited according to BIOMET 3i Specifications, as follows: |

| Description | Min. | Max. |
|---|---|---|
| A.) Platform Seating Diameter | 3.4 mm | 6.0mm |
| B.) Gingival Margin Diameter | 3.8mm | 16.0mm |
| C.) Gingival Margin Height External Hex 3.4mm Platform | 0.5 mm | N/A |
| C.) Gingival Margin Height Certain 3.4mm Platform | 0.25 mm | N/A |
| C.) Gingival Margin Height 4.1mm/5mm/6mm External Hex /Certain | 0.25 mm | N/A |
| D.) Total Height | 4.75mm | 15.0mm |
| E.) Angulations | 0° | 30° |

**Indications for Use:**

Encode® Patient Specific Dental Abutments made from oral scans provided from 3M ESPE Lava Chair Scanner and the 3M Lava COS (2.0) software are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. Encode® Patient Specific Dental Abutments are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

**Performance Data:**

Validation performed on scanning equipment and software to ensure accuracy of scanning models to produce the intended design as cleared in *K032263 & K052648.*

**Equivalence Data:**

Encode® Patient Specific Dental Abutments made from oral scans provided from 3M ESPE Lava Chair Scanner and the 3M Lava COS (2.0) software have the same intended use and indications, principles of operation, and technological characteristics as previously cleared BIOMET *3i* Encode® Patient Specific Dental Abutments. The additional option of oral scans as a source of digital images for existing design CAD/CAM software do not raise any new questions of safety or effectiveness. Validation data demonstrates that the modified process results in a finished device that is just as safe and effective as Encode® Patient Specific Dental Abutments that are currently cleared under *K032263 & K052648*. Thus, the Encode® Patient Specific Dental Abutments 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

Ms. Juliana Arias
Regulatory Affairs Specialist
BIOMET 3i
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

MAR 11 2011

Re: K101608
Trade/Device Name: Encode® Patient Specific Dental Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 24, 2011
Received: February 28, 2011

Dear Ms. Arias:

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,

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): ***K101608***

Device Name: Encode® Patient Specific Dental Abutments

Indications for Use:

Encode® Patient Specific Dental Abutments made from oral scans provided from 3M ESPE Lava Chair Scanner and the 3M Lava COS (2.0) software are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. Encode® Patient Specific Dental Abutments are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

| Prescription Use ___X___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sara Boyer

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

510(k) Number: K101608