**Summary of Safety and Effectiveness**

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*, Inc.<br>4555 Riverside Drive<br>Palm Beach Gardens, FL 33410 |
| **Contact** | Diana Taylor<br>Manager, Regulatory Affairs<br>Biomet *3i*, Inc.<br>4555 Riverside Drive<br>Palm Beach Gardens, FL 33410<br>Tel. 561-776-6857<br>Fax. 561-776-6852 |
| **Date Prepared** | August 21, 2007 |
| **Device Name** | BIOMET *3i* NanoTite™ Dental Implants |
| **Classification Name** | Endosseous dental implant |
| **Classification** | Class II, 21 CFR § 872.3640 |
| **Product Code** | DZE |
| **Predicate Device(s)** | K051461 - *3i* Osseotite (Nano CaP) Dental Implant |
| **Device Description** | BIOMET *3i* NanoTite Dental Implants cleared by K051461, K063341 & K063286 have both the proprietary OSSEOTITE acid-etched surface and NanoTite CaP Discrete Crystalline Deposition (DCD) surface treatment.<br><br>The devices themselves have not been modified since their original clearance. Specific performance claims for NanoTite Dental Implants are being modified. Two independent prospective randomized controlled studies provide clinical data to support the requested claims. |

JAN 31 2008

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| **Indications for Use** | BIOMET *3i* dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.<br><br>BIOMET *3i* NanoTite dental implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. |
| **Conclusion** | The clinical data submitted for the NanoTite dental implant compared to the control implant supports the modifications to specific performance claims requested within this premarket notification. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Ms. Diana Taylor
Manager, Regulatory Affairs
Biomet 3i, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K072363
Trade/Device Name: BIOMET 3i NanoTite Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 11, 2008
Received: January 17, 2008

Dear Ms. Taylor:

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

K072363



# Indications for Use

510(k) Number (if known): Unknown

Device Name: **BIOMET *3i* NanoTite Dental Implants**

Indications for Use:

BIOMET *3i* dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

BIOMET *3i* NanoTite dental implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

| 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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