K133049

JAN - 8 2014

3i T3® External Hex Dental Implants
510(k) Summary
December 18, 2013

I. **Company:** BIOMET *3i*™
4555 Riverside Drive
Palm Beach Gardens, Florida 33410
(561) 776-6700

Contact: Chris McKee
Regulatory Affairs Manager

II. **Proprietary Trade Name:** 3i T3® External Hex Dental Implants

III. **Classification Name:** Implant, Endosseous, Root-Form (21 CFR 872.3640)

IV. **Classification:** Class II

V. **Product Code(s):** DZE

VI. **Reason for 510(k)**
The purpose of this 510(k) was to expand BIOMET 3i™'s dental implant product line by adding dental implants with a multi-level surface topography like the existing 3i T3® Dental Implants but with an external connection like other BIOMET 3i™ product lines.

VII. **Product Description**
The 3i T3® External Hex Dental Implants are manufactured from commercially pure titanium and feature a roughened apex and traditional OSSEOTITE® coronal surface. In addition, the implants are offered with or without a nano-scale discrete crystalline deposition (DCD®) of calcium phosphate (CaP) surface treatment. The dental implants are basic screw-type designs available in either parallel walled or tapered body geometries. The implants are available in various platform options and feature an external hex connection for mating with associated Biomet 3i™ external connection restorative components. The implants are offered in a variety of diameters (3.25mm – 6.0mm) and lengths (Parallel walled: 6.5mm – 18.0mm, Tapered: 8.5mm – 15.0mm) to accommodate varying patient anatomy.

VIII. **Indications**
3i T3® 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.

3i T3® 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.

IX. **Summary of the Technological Characteristics**
The subject devices provide additional implant options for connection to existing Biomet 3i™ external hex restorative components. The primary change from the predicate 3i T3® devices in K122300 is that the connection geometry is an external connection instead of an internal

connection. The external connection is the same as the other predicate external connection dental implants. The materials, implant body designs (tapered and parallel walled), surface treatments and sizes are the same as the listed predicate devices.

X. Identification of Legally Marketed Devices

The design features, materials and indications for use of the subject devices are substantially equivalent to the predicate devices noted below.

- 3i T3® Dental Implants (K122300)
- OSSEOTITE® 2 External Hex Parallel Walled Dental Implants (K111216)
- OSSEOTITE® External Hex Dental Implants (K063286)

XI. Discussion of the Non-Clinical Testing

Non-clinical testing in the form of mechanical testing was performed on the worst case subject devices in the form of fatigue testing in accordance with ISO 14807:2007. The results were compared to the previously listed predicate devices in K063286. The subject devices met the pre-determined acceptance criteria.

XII. Conclusions

Based on the test results and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the previously listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 8, 2014

BIOMET 3i™
Mr. Chris McKee
Regulatory Affairs Manager
4555 Riverside Drive
Palm Beach Gardens, FL 33410

Re: K133049
Trade/Device Name: 3i T3® External Hex Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 18, 2013
Received: December 19, 2013

Dear Mr. McKee:

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 contact 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. 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,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K133049

Device Name: 3i T3® External Hex Dental Implants

Indications for Use:

3i T3® 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.

3i T3® 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 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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