K063286

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Jacquelyn A. Hughes, RAC Director, Regulatory Affairs & Quality Assurance Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6819 Fax. 561-514 6316 Email jhughes@3implant.com
Date Prepared	October 27, 2006
Device Name	*3i* OSSEOTITE® Dental Implants
Classification Name	Endosseous Dental Implants
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3640
Predicate Devices	*3i* OSSEOTITE Dental Implants K874590, K935544, K972444, K980549, K983347, K992334, K014235, K022009, K030164, K033430, K051461
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.

Device Description

The *3i* OSSEOTITE® Dental Implants are provided with the proprietary OSSEOTITE acid-etched surface which has been in commercial distribution since market clearance in 1995. Implants are offered in tapered and parallel-walled/straight designs, each design providing offerings for external hex connections. Additionally, the implants are offered in a trans-gingival design with an internal connection Implants are offered in diameters of 3.25, 3.75, 4.0, 5.0, and 6.0 in varying lengths from 7 mm to 20 mm. size appropriate cover screws are offered with each implant.

Indications for Use

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, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

In addition, when a minimum of 4 implants, ≥ 10mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.

Technological Characteristics

The design features and functions are identical to the currently available OSSEOTITE, OSSEOTITE NT®, OSSEOTITE XP® and TG OSSEOTITE®, and *3i* Implant Innovations implants and cover screws.

Performance Testing

Laboratory testing was conducted to determine device functionality and conformance to design input requirements, as well as FDA's *Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.* Risk analysis was conducted in accordance with ISO 14971. Specific performance claims for enhanced performance in poor bone (K980549), early loading (K983347), and use in smokers (K022009), and immediate loading (K030164) have received market clearance based on the OSSEOTITE clinical data in the respective submissions.

Conclusion

The *3i* OSSEOTITE Dental Implants are substantially equivalent to the dental implants described in the premarket notification submissions for the predicate

devices K879450, K935544, K972444, K992334, K980549, K983347, K014235, K022009, K030164, K033430 , K051461.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2007

Ms. Jacquelyn A. Hughes
Director, Regulatory Affairs & Quality Assurance
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K063286
Trade/Device Name: OSSEOTITE® Dental Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 12, 2007
Received: April 13, 2007

Dear Ms. Hughes:

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.

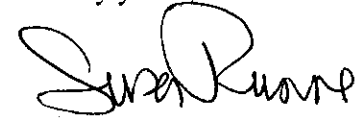
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for 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

Indications for Use

510(k) Number (if known): K063286

Device Name: OSSEOTITE® Dental Implants

Indications for Use:

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, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

In addition, when a minimum of 4 implants, ≥ 10mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.

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)

Susan Runner

...of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...(k) Number: K063286