SEP 15 2005

K051461

510(k) 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 § 807.93

Submitter	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Jacquelyn A. Hughes, RAC Director, Regulatory Affairs and Quality Assurance Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6819 Fax. 561-514-6316 Email jhughes@3iimplant.com
Date Prepared	May 25, 2005
Device Name	*3i* Nano CaP OSSEOTITE® Implants
Classification Name	Endosseous Dental Implant
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3640
Predicate Devices	K014235 - OSSEOTITE NT™ Dental Implants K972444 - *3i* Innovative Implants and Cover Screws K935544 – Threaded Self-Tapping Threaded Implants K980549 – OSSEOTITE Dental Implants K983347 - OSSEOTITE Dental Implants K022009 – *3i* Dental Implants K955428 – Hydroxylapatite (HA) Coated Endosseous Implants K031475 – *3i* OSSEOTITE NT Certain Implants K030614 - *3i* Implants K031632 - *3i* IOL Implants K041402 – OSSEOTITE NT Certain Implants K051189 – Prevail Implants

Device Description

The *3i* Nano CaP OSSEOTITE Dental Implants are provided with the proprietary OSSEOTITE acid-etched surface further treated with a deposition of nano-crystals of calcium phosphate. Implants are offered in both tapered and parallel-walled /straight designs, and each design provides offerings for either external hex or internal connections.

Indications for Use

The *3i* Nano CaP OSSEOTITE Dental Implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restoration 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, $\geq$ 10 mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.

Technological Characteristics

Substantial equivalence of the *3i* Nano CaP OSSEOTITE Dental Implants is based on:

1. Design features and functions which are similar to the currently available OSSEOTITE, OSSEOTITE NT, OSSEOTITE Certain, OSSEOTITE Certain NT, and Prevail Implants and *3i* Innovative Implants and Cover Screws.
The OSSEOTITE surface is enhanced by the presence of nano-crystals of calcium phosphate which is similar to the currently available Hydroxylapatite (HA) Coated Endosseous Dental Implants.

2. Performance testing. The proposed and currently marketed devices are identical in terms of size, biocompatible materials of construction, performance characteristics, and basic design.

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.

Conclusion

The ***3i*** Nano CaP OSSEOTITE Dental Implants are substantially equivalent to the above mentioned legally marketed predicate devices, which provide the same or similar functions, as well as technological characteristics. The indications for use and intended use are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2005

Ms. Jacquelyn A. Hughes
Director, Regulatory Affairs and Quality Assurance
Implant Innovations, Inc.
4555 Riverside Dr.
Palm Beach Gardens, Florida 33410

Re: K051461
Trade/Device Name: 31 Osseotite Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 11, 2005
Received: August 12, 2005

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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K051461

Device Name: *3i* 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, ≥ 10 mm in length, are placed in the maxilla and/or the mandible and splinted in the anterior region, immediate loading is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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

510(k) Number K051461