JUN 8 - 2005

K051189

DEVICE NAME

Device Trade Name	PREVAIL™ Implants
Common/Classification Name	Dental Implants

1.0 ADDRESS AND REGISTRATION FOR MANUFACTURING AND STERILIZATION SITES

Sponsor	Implant Innovations, Inc. 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel.: 561-776-6700
Official Correspondent	Jim Banic Regulatory Affairs Specialist Implant Innovations, Inc. Tel.: 561-776-6932 Fax.: 561-514 6316 Email: jbanic@3implant.com
Manufacturing Site	Implant Innovations, Inc. 4555 Riverside Drive Palm Beach Gardens, FL 33410 Registration No. 1038806
Sterilization Site	Ion Beam Applications (IBA) formerly Sterigenics 1148 Porter Avenue Haw River, NC 27258 Registration No. 1036836

2.0 CLASSIFICATION INFORMATION

Device Class	Class II
Classification Panel	Dental Devices Panel
Regulation Number	21 CFR §872.3640
Product Code	DZE

3.0 LEGALLY MARKETED DEVICE INFORMATION

The PREVAIL Implants are the subject of this 510(k) submission and are similar to the ones currently marketed and cleared in the following premarket notifications:

- K031632 – OSSEOTITE IOL Implants, cleared by letter dated September 16, 2003.
- K041402 – OSSEOTITE NT™ Certain 3.25mm Implants, cleared by letter dated June 16, 2004.
- K935544 – 3i Implants, cleared by letter dated March 13, 1995.

The proposed design modifications of the PREVAIL implants do not affect the intended use or alter the fundamental scientific technology of the device. Reference is made to a Comparison Chart contained in Section F of this premarket notification.

4.0 INTENDED USE/INDICATION 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 restoration and in partially or fully edentulous spans with multiple single teeth, freestanding bridges and to retain overdentures.

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

The intended use of the PREVAIL implants is identical to those for the predicate devices cleared in K031632.

6.0 DEVICE DESCRIPTION

The PREVAIL implants are the same as the OSSEOTITE IOL implants [K031632] designed with an internal and external hex connection. The PREVAIL implants will have the expanded collars and lateralized seating surface on both the natural tapered and parallel walled implants. The PREVAIL implants will be manufactured from Titanium Alloy per ASTM F-136 or Commercially Pure Titanium per ASTM F-67.

The PREVAIL implants will be available in lengths of 8.5mm to 15.0mm with a body diameter of 3.25 to 6.0mm. Reference is made to Section E for copies of engineering drawings. Catalog numbers are referenced in the following table.

Furthermore, the OSSEOTITE IOL implants [K031632] have been added to this submission, unmodified, in order to expand the indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Mr. Jim Banic
Regulatory Affairs Specialist
Implant Innovations, Incorporated
4555 Riverside Drive
Plam Beach Gardens, Florida 33410

Re: K051189
Trade/Device Name: Prevail Dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: May 6, 2005
Received: May 10, 2005

Dear Mr. Banic:

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 of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051189

Device Name: Prevail 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 restoration and in partially or fully edentulous spans with multiple single teeth, freestanding bridges and to retain overdentures.

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

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K051189