K042971

JAN 14 2005

ADMINISTRATIVE INFORMATION

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| Manufacturer Name: | Titan Implants, Inc.<br>18 Columbia Ave.<br>Bergenfield , NJ 07621<br>Telephone (201) 439-0027<br>Fax (201) 439-1145 |
| Official Contact: | Cyril Chen |
| Representative/Consultant: | Floyd G. Larson<br>PaxMed International<br>4329 Graydon Road<br>San Diego, CA 92130<br>Telephone (858) 792-1235<br>FAX (858) 792-1236 |

DEVICE NAME

| | |
|---|---|
| Classification Name: | Implant, Dental, Endosseous (DZE)<br>Abutment, Implant, Dental, Endosseous (NHA) |
| Trade/Proprietary Name: | TITAN Dental Implant System |
| Common Name: | Endosseous Dental Implant<br>Endosseous Dental Implant Abutment |

ESTABLISHMENT REGISTRATION NUMBER

The Establishment Registration number for Titan Implants, Inc. is 2249649. The Owner/Operator number is 9041410.

DEVICE CLASSIFICATION

FDA has classified endosseous dental implants as Class II devices (21 CFR 872.3640 according to revision 69 FR 26307, May 12, 2004). The product code for "Implant, Dental, Endosseous" is DZE. Endosseous dental implant abutments are Class II devices (21 CFR 872.3630). The product code for "Abutment, Implant, Dental, Endosseous" is (NHA). Endosseous dental implants and abutments are reviewed by the Dental Products Panel.

K042971



INTENDED USE

The TITAN Dental Implant System is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary and/or mandibular arch and to provide support for crowns, bridges or overdentures.

DEVICE DESCRIPTION

Design Characteristics

The TITAN Dental Implant System is comprised of 26 root-form solid screw-type implant designs and a broad range of abutment designs, all of which are based on existing dental implant systems that are cleared for marketing in the United States. Implant design features include external shapes that are cylindrical (15 designs), tapered (10 designs) and stepped (1 design). Both transgingival and submerged designs are included. External implant thread forms include V, square and buttress designs. Anti-rotational features include external and internal design elements. All implants are made from titanium or titanium alloys conforming to ASTM and ISO standards. Surfaces include as-machined surfaces, grit blasted and acid etched surfaces, surfaces treated with resorbable blast media (RBM) and surfaces coated with plasma-sprayed titanium (TPS) or hydroxyapatite (HA). Diameters range from 3.25 mm to 6.5 mm, and lengths from 5.0 mm to 20.0 mm..

Abutment designs include long and short conical abutments, stepped abutments, gold cylinder abutments, gold/plastic castable abutments and ball head abutments. Anti-rotational features include external and internal design elements. All abutments are made from titanium or titanium alloys conforming to ASTM and ISO standards or from gold alloy. Surfaces include as-machined surfaces and surfaces treated with titanium nitride. Platform diameters range from 3.25 mm to 6.5 mm.

Abutment screws appropriate to each implant/abutment combination, healing abutments, temporary abutments and laboratory components are included in the TITAN Dental Implant System.

Material Composition

The implants, abutments and accessories for the TITAN Dental Implant System are made from CP titanium Grades 2 & 4 conforming to ASTM F67 and ISO 5832-2, Ti-6Al-4V ELI alloy conforming to ASTM F136 and ISO 5832-3 or Ti-13Nb-13Zr alloy conforming to ASTM F1713. The surface of the threaded portion of the TITAN dental implants is one of the following: as-machined, grit blasted and acid etched, treated with resorbable blast media (RBM), coated with plasma-sprayed titanium or coated with plasma-sprayed hydroxyapatite (HA). Collar portions are smooth machined. The abutment surfaces are as-machined or coated with titanium nitride. In addition, one design of abutment screw is surface treated using the Tiodize process.

EQUIVALENCE TO MARKETED PRODUCT

For the purposes of FDA's regulation of medical devices, the TITAN Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices:

- Implant Innovations Osseotite Implants cleared on September 16, 2003 under K031632
- Implant Innovations TG Osseotite Implants cleared November 7, 2003 under K033430
- Bicon Dental Implant II cleared August 18, 1997 under K972029
- Bicon Dental Implant II 4.5 mm cleared January 11, 2000 under K994037
- Bicon Dental Implant II 6.0 x 5.7 mm cleared December 30, 2002 under K010185
- BioHorizons Maestro Dental Implant cleared September 16, 1997 under K972313
- BioHorizons Maestro Dental Implant cleared May 16, 2001 under K010458
- Frialit-2 Dental Implant cleared March 24, 2000 under K994376
- Friadent XiVE Dental Implant cleared July 2, 2002 under K021318
- INNOVA Endopore Dental Implant cleared October 2, 2003 under K032140
- INNOVA Endopore Dental Implant April 9, 2004 under K040714
- Lifecore Dental Implant cleared May 16, 2001 under K002037
- SteriOss (now Nobel Biocare) Replace Tapered Implant cleared March 5, 1997 under K964220
- SteriOss (now Nobel Biocare) Replace Cylindrical Implant cleared March 16, 1998 under K980439
- Straumann ITI Dental Implant System cleared March 31, 2003 under K030007
- Astra Tech Dental Implant System cleared February 8, 1994 under K931767.

The TITAN Dental Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- is packaged and sterilized using the same or equivalent materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Titan Implants, Incorporated
C/O Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K042971
Trade/Device Name: TITAN Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: October 25, 2004
Received: October 28, 2004

Dear Mr. Larson:

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.

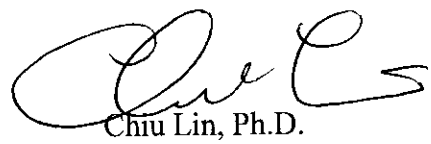
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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/dsma/dsmamain.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: K042971

Device Name: TITAN Dental Implant System

Indications for Use:

The TITAN Dental Implant System is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary and/or mandibular arch and to provide support for crowns, bridges or overdentures.

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 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: K042971