MAR 2 3 2005

SUMMARY OF K042715

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Titan Implants, Inc. 18 Columbia Ave. Bergenfield , NJ 07621 Telephone (201) 439-0027 Fax (201) 439-1145
Official Contact:	Cyril Chen

DEVICE NAME

Classification Name:	Abutment, Implant, Dental, Endosseous (NHA)
Trade/Proprietary Name:	TITAN Dental Implant Attachment
Common Name:	Endosseous Dental Implant Abutment
Predicate Device:	TITAN Titanium Abutment Heads for IMZ implants K003818

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. 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.

DEVICE DESCRIPTION

The Titan Dental Implant Attachments and accessories are an integrated system of endosseous implant abutments, which are designed to support prosthetic devices for partially, or fully edentulous patients. The system consists of a variety of dental implant abutments and accessories. The devices covered in this submission include abutments, combination transfer coping/permanent abutments and miscellaneous accessories.

INTENDED USE

The titanium abutment heads are intended for use with the various implants, and are designed for restorations where standard crown and bridge techniques are desired. The range of application is from full arch restoration to single tooth placement. These devices may also be used as a base for transitional appliances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2005

Mr. Cyril Chen
Technical Coordinator
Titan Implants, Incorporated
18 Columbia Avenue
Bergenfield, New Jersey 07621

Re: K042715
Trade/Device Name: TITAN DENTAL IMPLANT ATTACHMENTS
Regulation Number: 872.3630
Regulation Name: Endosseous Implant Abutments
Regulatory Class: II
Product Code: NHA
Dated: March 14, 2005
Received: March 15, 2005

Dear Mr. Chen:

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 (K042715):

Device Name: TITAN DENTAL IMPLANT ATTACHMENTS

Indication for use:

Abutments are intended to be placed into dental implants as support for prosthetic reconstructions such as crowns and bridges. The abutments are indicated for cemented restoration in areas of the mouth and used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

Prescription Use ✓ Yes ___ AND/ OR Over-The- Counter Use ___

(Part 21 CFR 801 Subpart D) (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)

Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital,

Infection Control, Dental Devices

510(k) Number K042715