

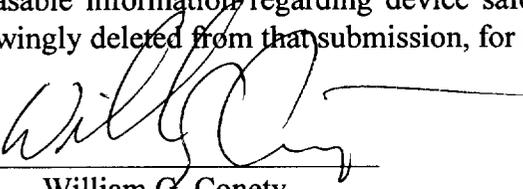
OCT 8 1999

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**510(k) SUMMARY**  
**3i TiN Coated Implants and Abutments**

To 510(k) Summary Requestor:

Information contained in this summary is from an original Pre-Market Notification [510(k)] submission, provided the United States Food and Drug Administration. No pertinent or known releasable information regarding device safety or efficacy has been intentionally or otherwise knowingly deleted from that submission, for this summary.



William G. Conety  
Regulatory Affairs

**PRE-MARKET NOTIFICATION: TiN Coating - Implants/Abutments**

- 01 CLASSIFICATION NAME:** 21 CFR Part 872.3640, **Endosseous Dental Implant\***
- 02 COMMON/USUAL NAMES:** Dental implants and fixtures; abutments; transmucosal abutments/elements; restorative/ prosthetic devices/components; abutment posts, cylinders, devices, fixtures, screws, etc.
- 03 PROPRIETARY NAME:** No specific marketing name is established.
- 04 CLASSIFICATION:** Class III
- 05 PERFORMANCE STANDARDS:** Unknown
- 06 BACKGROUND:**

The company has distributed a wide variety of commercially pure titanium and titanium alloy implants and abutment systems. Recently, there has been increased discussion concerning aesthetic improvements to implant supported restorations. It is reported, titanium implants and abutments under thin mucosal tissue can exhibit an unnatural grayish appearance, considered by some patients to be noticeable and therefore objectionable. Several competitor companies have incorporated TiN coatings to "harden" abutment component surfaces and in so doing, have enhanced esthetics.

Titanium Nitride ("TiN") coatings are widely used in orthopedic, dental, surgical and other medical device applications. It is a proven biocompatible, "ultra-hard" material that can greatly reduce wear of a variety of metal devices, including devices constructed of titanium. A search of medical/surgical related literature published on use of TiN coatings and tissue compatibility provides information to support a well established understanding that TiN is biocompatible when used in applications in the oral cavity.

**07 FORM and CONSTRUCTION:**

3i proposes to apply a TiN coating to abutment cylinder surfaces with exception of the implant mating surface interface area. On implants, the coating will be applied to coronal, transgingival collar area. Implant/abutment interface surfaces will not be coated. Current dimensional characteristics and specifications for implants and abutments to be TiN coated do not change. Cleaning, packaging and sterilization operations will be accomplished by the same means and under the same controls as non-TiN coated implants and abutments.

In clinical application, implant placement, abutment selection/preparation and restorative procedures do not change. With "prep-type" abutments, much of the area containing the TiN coating may actually be removed during the preparation processes in the dental laboratory. Restorative appliances incorporating TiN coated abutment systems will continue to be, screw or cement retained with no additional or other significant revisions in abutment preparation processes. The only visible outcome difference will be the appearance of the gold TiN color, where previously the non-coated titanium showed. Current sterilization means and processes do not change by addition of the TiN coating.

**08 DEVICE/DESIGN PERFORMANCE EVALUATION:**

The proposed TiN coating has been physically evaluated to determine adhesion to the titanium substrate and performance with cement retained restorative appliances.

Scratch adhesion (TiN to CP titanium): 2.5 - 2.75kg.

Adhesion of cement retained prosthetic to TiN: Visual observation of TiN abutments after removal of cemented copings revealed no de-lamination or loss of coating. Removal of cemented copings from TiN coated abutments was equal to or greater than copings from non-coated abutments with a significantly smaller standard deviation. TiN coating was not removed from substrate, when scraped with a steel dental curette.

**09 SUBSTANTIAL EQUIVALENCE:**

TiN-coated abutments/implants are substantially equivalent to current 3i implant/abutments as well as competitive systems using TiN coatings. TiN-coated implants/abutments differ from original implant/abutment systems only in use of the TiN.

## 10 INDICATIONS FOR USE:

Indications for use of TiN coated implants and abutments do not change from non-coated implants and abutments, indicated for surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.

## 11 CONTRAINDICATIONS, WARNINGS, ETC:

Implants/abutments should not be used where remaining jawbone is too diminished to provide adequate width or height to surround the implant. Lack of osseointegration or subsequent implant failure may occur in cases where there is: Insufficient available bone or there is poor bone quality, poor oral hygiene, heavy smoking or tobacco use; Medical conditions such as blood disorders, infection(s), or vascular impairment at surgical site, uncontrolled diabetes; Heavy smoking or tobacco abuse, drug or alcohol abuse, chronic high dose steroid therapy; medical conditions such as blood clotting disorders, current or ongoing anticoagulant therapy, metabolic bone disease or other metabolic or systemic disorders may adversely affect bone or wound healing.

For safe/effective use, it is suggested specialized training be undertaken since surgical technique to place dental implants are highly specialized and complex procedures. Improper patient selection and/or surgical technique can cause implant and/or abutment failures with possible loss of supporting bone. Thorough screening of prospective implant candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT scans and tomogram may also be beneficial.

Loss of implant anchorage (failure to integrate) and loss of the prosthesis are possible occurrences after surgery. Lack of quantity or quality of remaining bone, infections, poor patient oral hygiene or cooperation, and generalized diseases (diabetes, etc.) are some potential causes for loss of anchorage. The implant procedure has risks, including localized swelling, dehiscence, tenderness of short duration, edema, hematoma, or bleeding. Numbness of the lower lip and chin region following lower jaw surgery, and of the tissue beside the nose following upper jaw surgery, is a possible side effect of the surgery. Though most probably of a temporary nature, in very rare cases, the numbness has been permanent. Gingival/mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.

## LABELING:

Specific labeling is not finalized. However appropriate distinction between TiN coated and non-coated devices will be made

\_\_\_\_\_ End Summary \_\_\_\_\_



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 8 1999

Mr. William G. Conety  
Regulatory Affairs  
Implants Innovations®, Incorporated  
4555 Riverside Drive  
Palm Beach Gardens, Florida 33410

Re: K992334  
Trade Name: Endosseous Implants and Abutments- Tin  
Coating  
Regulatory Class: III  
Product Code: DZE  
Dated: July 9, 1999  
Received: July 13, 1999

Dear Mr. Conety

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

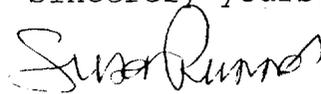
Page 2 - Mr. Conety

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



fx

Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K

Page 1 of 1

Device Name: Endosseous Implants and Abutments - TiN Coating

INDICATIONS FOR USE:

Endosseous implants and abutments are indicated for surgical placement into the upper and lower jaw arches as permanent support for prosthetic appliances, to restore a patient's masticatory function. Proposed Titanium Nitride ("TiN") coating applied to implants/abutments improves the overall esthetics of the completed restoration.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Runner*

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

510(k) Number R9923321

Prescription Use  OR Over-the-Counter Use:  Per 21 CFR 801.109)