IMPLANT INNOVATIONS®

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K960577

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION TO SUPPORT A DETERMINATION OF SUBSTANTIAL EQUIVALENCE OF IMPLANT INNOVATIONS, INC'S. SINGLE TOOTH ABUTMENT SYSTEM

1. CLASSIFICATION NAME: Unknown

2. COMMON/USUAL NAMES: Standard Abutment and Screw, Non-Rotating Gold Cylinder Abutments, Abutment Head Post, Transmucosal Element/Abutment, Cera-One Abutment (Nobel Bio-Care).

3. PROPRIETARY NAME: 3i STA Abutment (System)

4. ESTABLISHMENT REGISTRATION NUMBER: 1038806

5. CLASSIFICATION: Abutments and restorative components for Endosseous Dental Implants, in and by themselves have not been classified. Endosseous dental implants, per 872.3640 are class III devices. As an extension of an implant or used in the restoration of an endosseous dental implant, abutments and restorative components may be classified as class III devices.

6. PERFORMANCE STANDARDS: Not applicable.

7. LABEL/LABELING MATERIALS: Product labeling, instructions for use and promotional materials have yet to be developed. Labeling and instructions for use will follow a similar format as other 3i Abutment Systems for both sterile and non-sterile products and at a minimum contain the following:

NON-STERILE PRODUCT:

Product Catalog Number
Product name, nomenclature and relevant sizes
Product lot number
3i address and phone numbers

"For autoclaving and Chemiclave (R) only, Indicator turns brown when subjected to autoclave and Chemiclave (R) conditions."

STERILE PRODUCT:

In addition to the above, the following is added for

sterile devices; "Contents sterile unless seal is opened or damaged"

8. FORM: The STA System is a multi-component system consisting of abutment cylinders/screws, temporary healing caps, temporary cylinders for provisional restorations, impression copings, laboratory analogs and gold copings (cylinder) for cement retained restorations.

   The STA system is not significantly different from other 3i abutment systems except that it is designed specifically for single tooth CEMENT RETAINED RESTORATIONS. The STA system is designed to be used with standard size implants and is offered in an assortment of transmucosal tissue heights. The abutment cylinder also features the 3i "Gold Standard ZR" minimal micro-movement design which permits a tighter fit between components, further reducing inter-component "micro-movement", often attributed to abutment screw loosening and fracture.

   The STA Cylinder is constructed of titanium. (NOTE: The abutments may also be constructed of titanium alloy Ti1313). The Abutment "Uniscrew" is constructed of Titanium Alloy and Gold/Palladium Alloy, and will be distributed based on customer preference. The STA Cylinder and screw may be distributed either sterile or non-sterile. If sterile, packaging will consist of the 3i "Asyst" packaging and delivery system and sterilization accomplished by an FDA registered Co60 Irradiation sterilization facility following AAMI guidelines for a minimum SAL of 10 to the minus 6. Validation of sterilization is accomplished as specified by the AAMI (Association for the Advancement of Medical Instrumentation) Guidelines, Method 1 and the European Harmonized Standard EN 552.

   Non-Sterile packaging will consist of a heat sealed autoclavable pouch.

   The STA System consists of other supporting tools and components designed specifically for the system.

   STA Temporary Caps;
   STA Temporary Cylinders for provisional components;
   STA Impression Copings, STA Lab Analogs; and,
   STA Gold Copings (Cylinders).

   All 3i STA system supporting components are distributed in individual autoclavable pouches and are cleaned, non-sterile. All Components are designed to be autoclavable.

   STA Temporary Caps constructed of CP Titanium (or Ti1313), are designed to fit directly over the STA Cylinder and are used to form and maintain soft tissue

opening after placement of the abutment. They are held to the abutment by screwing the cap directly into the Abutment Screw.

The STA Temporary Cylinders are designed for use in the construction of transitional, cement retained fixed restorations and are used in place of gold components during bite registration and while final restorations are being fabricated. Unlike the Nobel Bio-Care "Cera-One" plastic temporary cylinder components, the STA Temporary Cylinder is constructed from Titanium alloy for greater strength and tighter tolerance capabilities. Acrylic or composite material may be applied directly to the surface

The two-piece STA Impression Copings are designed specifically for use with the STA Cylinder and permit impressions to be made immediately after abutment placement and prior to healing cap placement. The STA impression coping is constructed of stainless steel.

The STA Laboratory Analog is manufactured from Stainless Steel and is designed to produce a replica of both the 3i STA Abutment or the Nobel Bio-Care "Cera-One" (TM) abutment. It's Stainless Steel construction provides a more durable analog and allows for use as a fixing device during soldering and when investing for casting. It's larger design provides better fixation in stone when using soft tissue models.

The STA Gold Coping is used to form the final restoration. It fits directly over the STA cylinder and is designed to be used with a "non-permanent cement of the clinicians choice. It's construction of gold alloy helps prevent "greening" of porcelain and provides for a very workable processing range. It is recommended that high noble alloys be used for casting.

9. SUBSTANTIAL EQUIVALENCE: 3i's STA Abutments are substantially equivalent to 3i's Standard, Tapered or Conical Abutment systems, 3i's Abutment Posts and Nobel Bio-Care's "Cera-One" abutment systems, in that the components are constructed of the same basic materials (with exception to Nobel Bio Care's use of plastics) and are of similar design. Indications for use of the 3i STA system do not substantially differ from those offered by Nobel Bio-Care or from 3i's other abutment system, except that the system is designed exclusively for cement retained, single tooth restorations.

10. INDICATIONS FOR USE: 3i's STA System is indicated for use in cement retained, single unit restorations. "The 3i Implant System (including abutments) is designed for use in dental implant surgery. The 3i Implant System includes a variety of types and sizes of specially

designed bone-implantable titanium and titanium alloy implants and abutments. The implants are surgically inserted into the upper and/or lower jawbones and upon healing an abutment may be placed on the implant, extending the implant's coronal aspect through the soft tissues and into the oral cavity. A prostheses is then attached to the Abutment(s).

A successfully osseointegrated implant will achieve a firm and direct connection between the living bone and the surface of the titanium or titanium alloy implant when surgically implanted under controlled conditions, per well known clinical studies.

11. CONTRAINDICATIONS:

3i implants and Abutments should not be used in cases where the remaining jaw bone 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, poor bone quality, poor oral hygiene, heavy smoking or tobacco abuse, or medical conditions such as blood disorders or uncontrolled diabetes.

12. WARNINGS:

For safe and effective use of 3i implants and abutments, it is strongly suggested that specialized training be undertaken since the surgical techniques required to place dental implants are highly specialized and complex procedures. Improper patient selection and technique can cause implant and/or abutment failure with possible loss of supporting bone.

13. PRECAUTIONS:

Thorough screening of prospective implant candidates must be performed. Visual inspection as well as panoramic and pariapical radiographs are essential to determine anatomical landmarks, occlusal conditions, pariodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT Scans, and tomograms may also be beneficial.

14. ADVERSE EFFECTS:

Loss of implant anchorage (failure to osseointegrate) 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.

15. SURGICAL COMPLICATIONS:

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 it would most probably be 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.

16. PRE-MARKET NOTIFICATION CERTIFICATION AND SUMMERY FOR SUBMISSION:

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for Endosseous Dental Implant systems, including abutment systems. Failure to osseointegrate or loss of osseointegration can be caused by improper patient selection (patients with systemic diseases which affect bone physiology, patients with habits such as bruxing or clenching, patients who are physically or psychologically unable to carry out proper implant hygiene, heavy smoking or alcohol use), by improper surgical technique (overheating of bone) or improper case planning or restorative technique (overloading of implants through improper placement, use of an insufficient number of implants or excessive cantilever). Improper implant processing by the manufacturer or improper handling by the customer, resulting in contamination, can also effect osseointegration.

Fracture of implants can occur, particularly in implants with apical cross-holes. Fracture occurs either on insertion of screw-type implants due to excessive torque (improper surgical technique such as an error in drill selection) or in service due to loss of bone.

Fracture of abutments and abutment screws occurs in implant systems and is usually attributed to factors within the control of the implant team, such as lack of passive fit of the restoration or excessive cantilever, or within the control of the patient, such as bruxing.

Other types of safety and efficacy problems which have been observed for endosseous dental implant systems are

local soft tissue degeneration and bone resorption, paresthesia, perforation of the maxillary sinus, perforation of labial and lingual plates, local and systemic infection, prosthetic framework fracture, nerve injury, bone fracture, injury to adjacent teeth and their supporting bone, oroantral or oronasal fistula, gingival hyperplasia, soft tissue overgrowth, perforation of the gingiva by the healing screw, mucosal abscess, displacement of the implant into the mandibular canal, hemorrhage of the floor of the mouth due to transection of the sublingual artery and breakage of drill tip, requiring surgical removal.

_____ end _____

William G. Conety
Director, Regulatory
Affairs/Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1997

Mr. William G. Conety
Director, Regulatory Affairs/Quality Assurance
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K965077
Trade Name: Single Tooth Abutment System
Regulatory Class: III
Product Code: DZE
Dated: December 14, 1996
Received: December 17, 1996

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 (Premarket 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 premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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) 594-4618. 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 at (301) 443-6597.

Sincerely yours,

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

Enclosure

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INDICATIONS FOR USE

510(k) Number: _____

Device Name: Single Tooth Abutment (STA) Systems for Cement Retained Single Tooth Restorations.

INDICATIONS FOR USE:

The STA abutment system is indicated for use on properly placed and healed dental implants, to extend the coronal aspect of the implant through soft gingival tissues into the oral cavity to provide the attachment mechanism for cement retained, single tooth restorations to restore a patient's chewing function.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K960577

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)