K972444

AUG 26 1997

510(k) SUMMARY

"ROCKET II" ENDOSSEOUS DENTAL IMPLANT SYSTEMS DESIGN MODIFICATION OPTION

01. BACKGROUND INFORMATION:

Current 3i implants are designed and constructed with a smooth polished 2.0mm collar and "External Hexed" coronal aspect, that is normally positioned surgically, just below the crest of the ridge, placing the coronal external hexed surface even with the crest of the ridge. To this "hexed" coronal aspect, a healing abutment, final abutment or UCLA Gold Cylinder is attached, completing the restorative aspect of the implant procedure, providing natural ridge and emergence profiles and very natural and aesthetically pleasing restorations. All current 3i implants use this very standard hexed implant design.

The "Two-Part Implant System consists of the implant itself and any of a variety of transmucosal, temporary healing and permanent abutment systems and devices. Current 3i systems, both threaded and plasma sprayed cylindrical designs are used extensively in traditional two-stage surgical protocols and single surgical protocols, using the extensive line of 3i Temporary Healing Abutment Systems. These systems and procedures are well accepted and provide excellent clinical benefit with very predictable outcomes.

The ITI Straumann Dental Implant System does not incorporate this "traditional" hexed coronal aspect. This system incorporates an internal tapered aspect in the coronal aspect of the implant. This taper (ITI identifies as a "Morse Taper") provides a much greater surface area for frictional interface between the implant and the connecting components This feature significantly reduces the potential for abutment loosening and helps to protect abutment retaining threads from functional loading.

The 3i "Rocket II" design modification provides the current 3i implant and restorative systems that incorporates a similar, internally tapered, integral transmucosal aspect. This feature will permit a One-Stage Surgical procedure, in which the implant will be placed at or just below the soft mucosal tissue surfaces. As with the single-stage procedure using two-stage implant systems, instead of using a temporary healing abutment on the implant, a simple cover screw will be used during the healing stages.

Upon healing, the cover screw will be removed and the implant restored using conventional techniques and components. The components for the modified implant will be identical to current 3i abutment systems, but will feature the opposing modified "Morse" tapered aspect of the implant

No other aspect of the implant or restorative systems will change and no new materials, processes, devices or indications for use or performance claims are being made at this time. This submission covers only the requested design modification to the coronal aspect of 3i's current threaded (Standard Threaded, Self-Tapping and "OsseoTite" surface (acid treated) and Titanium Plasma Sprayed (TPS) Cylindrical implant designs .

02. **CLASSIFICATION NAME**: Endosseous Dental Implant

03. **COMMON/USUAL NAMES**:

Dental implants, Screw Type Implants, Cylinder Implants, Press-Fit Implants, Single Stage Dental Implant, Innovative Implants and Cover Screws, Branemark Implants, ITI Implants.

04. **PROPRIETARY NAME**: 3i Innovative Implants and Cover Screws.

NOTE: This submission covers a proposed design modification referred to as the "Rocket II" design feature.

05. **ESTABLISHMENT REGISTRATION NUMBER**: 1038806

06. **CLASSIFICATION**:

Endosseous dental implants, per 872.3640 are class III devices. Date PMA or Notice of Completion of a PDP is required but no effective date has yet been

established for the requirements for Premarket approval.

07. **PERFORMANCE STANDARDS**. Not applicable.

08. **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 sterile implant systems and will at a minimum contain the following:

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

09. **FORM**:

The proposed "Rocket II" implant design consists of the current 3i designs for a commercially pure titanium, screw-type implant (3i Standard Threaded, Self-Tapping or titanium alloy cylindrical implant, plasma sprayed with Commercially Pure Titanium, modified to include the extended, internally tapered coronal aspect, very similar to the ITI Straumann Dental Implant System. This will be a modified 3i design and will be offered as an option to current 3i implant and restorative systems. All aspects of the proposed design modification are related to the coronal aspect of the implants. No other implant design feature, material or processing aspect is being altered.

"Rocket II" modified threaded implants will be available in Standard Threaded or Self-Tapping ("ICE" Incremental Cutting Edge) designs with either machined or "OsseoTite" (acid etched) surfaces, in identical sizes as currently available: Diameters between 3.25 and 6.00 mm's and lengths between 7.0 and 20.0mm's. The polished, extended coronal aspect of the implant is of various lengths between 1.0 and 4.0 mm's to provide the clinician a variety of transmucosal options .

The "Rocket II" design modification provides an implant that permits single surgical stage placement with coronal aspect of cover screw at or just below the mucosal tissue surface.

The internal aspect of the transmucosal aspect of the implant consists of a modified "Morse" taper with an interlocking "Hex" feature for two-piece abutment components. With the exception of the interlocking hex feature, the coronal aspect of the "Rocket II" design is very similar to what Straumann markets as its "Morse Taper".

The "Rocket II" design modification permits a single stage surgical protocol utilizing current 3i drilling armamentarium that reduces chair time for both patient and clinician. The modified "Morse" taper design, provide a much greater frictional surface area for substantially greater frictional interface between implant and restorative screws and components, that helps to further reduce "micro-movement" between components. It is well documented in the literature, that "micro-movement" is a contributing cause to screw loosening and subsequent fracture.

Restorative options for the "Rocket II" design modification will incorporate nearly all 3i restorative tools and components, with the only differences related to incorporation of the matching, interference-fit, modified taper and interlocking HEX feature.

Implants with the "Rocket II" design modification will be packaged in the standard dual-tray package and distributed presterilized to a Sterility Assurance Level of 10^{-6}. Sterilization validation is accomplished as specified by AAMI and other harmonized international standards.

10 SUBSTANTIAL EQUIVALENCE.

The proposed design modification "Rocket II" combines the internally tapered, single surgical stage superior aspect currently offered in the Implants of the ITI Straumann Dental Implant System with the Standard Threaded, Self-Tapping and TPS Cylindrical implant body designs currently available from 3i. Thus, the proposed Rocket II design implants are in fact, substantially equivalent to current dental implants from 3i and ITI Straumann.

11. INDICATIONS FOR USE.

Indications for use of the 3i Endosseous Dental Implant Systems are not altered by this submission. An Endosseous Dental Implant is indicated for

surgical placement in the upper or lower jaw arches, to provide a root form means for prosthetic appliance attache to restore a patient's chewing function. 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.

There has been no change in the indications for use as those specified in the original respective submissions.

12. 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 or poor bone quality, poor oral hygiene, heavy smoking or tobacco abuse, or medical conditions such as blood disorders, infection(s), 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 which may adversely affect bone or wound healing or cases in which the available bone is too diminished to provide adequate width or height to adequately hold implants and restorative appliances.

13. 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.

14. PRECAUTIONS:

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, parodontal

status, and adequacy of bone. Lateral cephalometric radiographs, CT Scans, and tomogram may also be beneficial.

15. **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.

16. **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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 26 1997

Re: K972444
Trade Name: 3I Innovative Implants and Cover Screws
Regulatory Class: III
Product Code: DZE
Dated: June 23, 1997
Received: June 30, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

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

IMPLANT INNOVATIONS®

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INDICATIONS FOR USE

510(k) Number: K972444

Device Name: "Rocket II" 3i Endosseous Dental Implant System
Design Modification

INDICATIONS FOR USE:

Indications for use of the 3i Endosseous Dental Implant Systems are not altered by this submission. An Endosseous Dental Implant is indicated for surgical placement in the upper or lower jaw arches, to provide a root form means for prosthetic appliance attachment to restore a patient's chewing function.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972444

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