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3i
IMPLANT INNOVATIONS

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510(k) Summary

510(k) SUBMISSION: **MATERIAL CHANGE (ADDITION) - TITANIUM 13-NIOBIUM 13-ZIRCONIUM (Ti-13Nb-13Zr) FOR TRANSMUCOSAL ABUTMENTS FOR THE 3i ENDOSSEOUS DENTAL IMPLANT SYSTEM.**

1. CLASSIFICATION NAME: Endosseous Dental Implants

2. COMMON/USUAL NAMES: Transmucosal Abutments and Screws, Transmucosal Elements, Abutment Cylinders and Screws, Abutments, Conical, Standard, Temporary, Tapered, etc.

3. PROPRIETARY NAME: Standard Abutments and Screws, Conical Abutments and Screws, Emergence Profile Abutments and screws, Tapered Abutments, Temporary Healing Screws and Abutments, Posts and Cylinders, Non-Rotating Abutments, Abutment Posts, STR (Single Tooth Restoration) Abutments, "O-Ring" and "Dal-Ro" Abutments.

4. CLASSIFICATION: Transmucosal Abutments are not in and by themselves classified. They are however, considered an integral part of the implant and are therefore classified as the implant. Endosseous dental implants, per 872.3640 have been classified as class III devices. PMA's may be required for some or all designs of endosseous dental implants including abutments, but no effective date has been established for the PMA submission.

5. PERFORMANCE STANDARDS: Not applicable at this time.

6. FORM: 3i's various abutment systems have historically been constructed of CP Titanium per ASTM specifications. This material change covers all styles and sizes of transmucosal abutments as listed herein, and pertains exclusively to a new alloy, that will be used in the production of the abutment components; from CP Titanium, to a Titanium, Niobium, Zirconium (Ti-13Nb-13Zr).

   Abutment systems include:

Standard Abutments	Tapered Abutments
Emergence Profile Abutments	Temporary Healing Abutments
Conical Abutments	Abutment Posts
Pre-Angled Abutments	Overdenture Abutments
Temporary Screws	Temporary Cylinders

6a. **NEW MATERIAL - Ti1313:**

Ti1313 is a titanium alloy consisting of Titanium, Niobium and Zirconium. Extensive physical and biological testing of the Alloy has been performed and the material is currently used in orthopedic applications. It recently received distribution clearance through the Pre-Market Notification process for 3i's Endosseous Dental Implants.

Physical testing by both the developer of Ti1313 and Implant Innovations, Inc. indicates an improvement in fatigue properties over commercially pure titanium which has previously been used in the construction of the transmucosal abutment and retaining screw systems.

For Abutment Systems included in this submission, there is no change in manufacturing or processing operations from those employed using the original titanium material.

Sterilization (where indicated) shall be accomplished using Co60 Irradiation, at a minimum dose of 25.0 kGy (2.5 mRads), achieving a Sterility Assurance Level (SAL) of 10(-6). Validation of sterilization process is accomplished as specified by the AAMI (Association for the Advancement of Medical Instrumentation) Guidelines and the Harmonized European Standard EN 552.

Irradiation sterilization is accomplished by an FDA registered irradiation sterilization facility.

7. LABEL/LABELING MATERIALS: The proposed material change will not necessitate revisions to device labeling or instruction sheets, other than catalog number and description, stating the new material.

8. SUBSTANTIAL EQUIVALENCE:

The material change has not alter the previously obtained substantial equivalence determination, for the various abutment systems. This is based on the fact that there has been no change in component design, other than the proposed change to Ti1313, and there are no other changes in manufacturing or processing. 3i is making no claims relative to these changes at this time, and indications for use of the various abutment systems have not changed.

9. INDICATION FOR USE:

Abutments are designed for use in dental implant surgery. The 3i 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 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.

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 or poor bone quality.

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 SUMMARY 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.

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 (over-loading 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.

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