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INNOVATIONS®

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Exhibit 8

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION TO SUPPORT A DETERMINATION OF SUBSTANTIAL EQUIVALENCE OF IMPLANT INNOVATIONS' Ti1313 THREADED IMPLANTS

510(k) SUBMISSION: **MATERIAL CHANGE - TITANIUM ALLOY (Ti1313), FOR SCREW FORM ENDOSSEOUS DENTAL IMPLANTS.**

1. CLASSIFICATION NAME: Endosseous Dental Implants

2. COMMON/USUAL NAMES: Standard Threaded Implants, Self-Tapping Threaded Implants, Miniplants (TM).

3. PROPRIETARY NAME: 3i Standard Threaded Implant. 3i Self-Tapping Threaded Implants and 3i Miniplant (TM) Implants. All included in the original Pre-Market Notification, titled "Innovative Implants and Cover Screws".

4. CLASSIFICATION: 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 in the future, but no effective date has been established for PMA submission.

5. PERFORMANCE STANDARDS: Not applicable at this time.

6. FORM: 3i's Endosseous screw type dental implants have historically been constructed of Commercially Pure (CP) Titanium, and are available in diameters between 3.25 and 6.00mm and lengths between 7.00 and 20.0mm.

   This change covers all styles, sizes, and lengths of 3i's screw type implants and pertains to a new alloy, that will be used in the production of the implants; from previously recognized Commercially Pure (CP) Titanium, to a Titanium Alloy identified as Ti-13Nb-13Zr.

   Extensive physical and biological testing of the Alloy Ti-13Nb-13Zr has been performed by the developer and is currently used in orthopedic implant applications.

   There is no change in the manufacturing or processing operations from those employed using the original material. The implants are machined, finished, cleaned packaged and sterilized. A placement instrument and cover

screw (where specified), will be included with the implant.

Sterilization shall be accomplished using Co60 Irradiation, at a dose providing for a Sterility Assurance Level (SAL) of ten to the minus six.

Validation of sterilization shall be accomplished as specified by AAMI (Association for the Advancement of Medical Instrumentation) Guidelines.

Irradiation sterilization shall be accomplished by an FDA registered Irradiation sterilization facility.

7. LABEL/LABELING MATERIALS: The proposed process changes will not necessitate a revision to the device labeling or instruction sheets, other than catalog number and description, stating Ti-13Nb-13Zr instead of Commercially Pure Titanium. There are no promotional materials in development at this time.

8. SUBSTANTIAL EQUIVALENCE:

   This material change will not alter the previously obtained substantial equivalence determination for the 3i threaded implants. This is based upon the fact that there has been no change in the implant design, other than the proposed change to Ti-13Nb-13Zr, 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 3i threaded implant system have not changed and do not substantially differ from those offered by other dental device manufacturers.

9. INDICATION FOR USE:

   "The 3i Implant System 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. These implants are surgically inserted into the upper and/or lower jawbones.

   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.

10. CONTRAINDICATIONS:

    3i implants 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.

11. WARNINGS:

For safe and effective use of 3i implants, 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 failure and/or loss of supporting bone.

12. 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.

13. 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.

14. 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.

15. 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 (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.

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