3i
IMPLANT INNOVATIONS

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510(k) SUMMARY

NEW INDICATION FOR USE: SINGLE STAGE SURGERY USING DEVICES ORIGINALLY INDICATED FOR A TWO-STAGE SURGICAL PROCEDURE.

To the Requestor:

This information is taken directly from the original Pre-Market Notification [510(k)], submission, provided to the United States Food and Drug Administration. No information regarding safety or efficacy has been deleted from that submission, for this summary.

1. CLASSIFICATION NAME: Endosseous Dental Implants

2. COMMON/USUAL NAMES: Standard Threaded Implants, Self-Tapping Threaded Implants, Titanium Plasma Sprayed Cylindrical Implants, Miniplants (TM), with 1 and 2 Piece Temporary Healing, Emergence Profile (EP) Abutments.

3. PROPRIETARY NAME: 3i Standard Threaded Implant, Self-Tapping Threaded Implants and 3i Miniplant (TM) Implants. 3i Emergence Profile (EP) Temporary Healing Abutments.

   The 3i implant system was submitted in a Pre-Market Notification that has since been amended and modified by subsequent submissions. The 3i implant system was originally determined substantially equivalent on or about May 11, 1988. For the purpose of this submission, all 3i implants and One and Two Piece Temporary Healing, Emergence Profile (EP) Abutments are to be considered.

4. CLASSIFICATION: Endosseous dental implants (including abutments), per 872.3640 have been classified as class III devices. PMA's may be required for endosseous dental implants in the future, but no effective date has been established for such submissions.

5. PERFORMANCE STANDARDS: Not applicable at this time.

6. PRIOR INDICATIONS FOR USE: The 3i Implant System is designed for use in dental implant surgery. It includes a variety of types and sizes of specially designed bone implantable titanium and titanium alloy implants, including Standard and Self-Tapping Threaded Screw-Type and cylindrical press-fit implants with Titanium Plasma-Sprayed or Hydroxylapatite coatings. These implants are surgically inserted into the upper and/or lower jawbones.

   Temporary Healing, Emergence Profile (EP) Abutments were designed to be attached to the implant at a second stage surgical procedure, after a sufficient healing time for the implant/bone interface to form. Healing abutments were placed to help form the soft tissues to the proper diameter of the final restoration, creating a natural Emergence Profile of the prosthesis.

   A successfully integrated 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.

   Historically, the process for placing an implant, through final prosthesis, required a minimum of two surgical procedures. Stage one surgery included all activities required to place an implant/cover screw into the bone and suturing the mucoperiosteal flaps over the implanted devices. A healing period of between three and six months (or longer) followed, after which the site was surgically reopened (second stage surgery), and temporary healing abutments, provisional prosthetic components or final abutments were placed. Again, the mucoperiosteal flaps were sutured closed around the abutments and a healing period allowed for the soft tissues to heal.

7. PROPOSED NEW INDICATION FOR USE: Most clinicians recognize the need to protect the implant from premature loading throughout the required healing period. They also recognize the benefits of a single surgical procedure in cases that provide adequate protection of the implant/ healing abutment; such as with use of a modified, soft relined denture or a bridge, preventing mastication forces from affecting the implanted devices.

   In such cases, clinicians have used "Single-Stage" implant systems such as "The ITI Dental Implant System" distributed by The Straumann Company or, the "Immediate-Load Implant" distributed by Sargon Enterprises, Inc., as well as others, or have utilized two-stage implant systems offering temporary healing abutments, such as the 3i Implant/EP System.

A single-stage surgical process by which a 3i implant is placed into the bone and a 1 or 2 piece (EP) Temporary Healing Abutment is immediately attached to the implant, may be considered in those cases where the implant and healing abutment can be adequately protected from mastication forces throughout the healing period, by opposing dentition, denture or bridge that if required, may be modified to provide such protection.

The EP Temporary Healing Abutment may be a one or two piece abutment and, will be removed after the implant is firmly anchored into the healed implant site, without surgically altering the soft tissues.

Upon placement of the implant, instead of a cover screw, a Temporary (EP) Healing Abutment, that is of suitable height for the soft tissues, is secured to the implant. The mucoperiosteal flaps are then sutured closed around the healing abutment. During the healing phase, the soft tissues form to the diameter and contours of the healing abutment, forming the tissues to the "more natural emergence profile". This benefits both patient and surgeon in that only one surgical procedure is required. Both bone and soft tissues heal during the same time period, shortening the entire implant/reconstruction process by several months and reducing the chance for infection or other complications attributed to surgery.

Upon proper healing, impressions are taken using the 3i EP Impression system (K934126), and temporary or final prosthesis fabricated. No further surgery is required.

8. CONTRAINDICATIONS: A single stage surgical procedure using 3i implants and healing abutments is not indicated in cases where remaining bone or soft tissues are too diminished to provide adequate width or height to secure or surround the implant/abutment. Lack of integration and subsequent implant failure may occur in cases where there is an insufficient quantity of bone, poor bone quality, poor oral hygiene, heavy smoking/tobacco abuse, or numerous medical conditions including blood disorders and uncontrolled diabetes (See Sections 9-12).

   A single surgical stage process utilizing 3i implants and healing abutments is not indicated in cases where the implants cannot be adequately protected from premature loading by mastication forces throughout the required healing period. Protection may be obtained by the use of a modified, soft relined denture or a bridge.

9. 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.

10. 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.

11. 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.

12. 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 numbness has been permanent. Gingival/Mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.

13. LABEL/LABELING MATERIALS: The proposed new indication for use will not necessitate a revision to the device labels. Instruction sheets and marketing materials will be developed to reflect the use of the EP Temporary Healing Abutments in conjunction with 3i Implants at Stage 1 surgery. This material will specify that in those cases where the implant/abutment can be adequately protected from premature loading and mastication forces throughout the normal healing periods, a single stage surgical protocol may be considered.

14. SUBSTANTIAL EQUIVALENCE: A single-stage surgical protocol utilizing the 3i Implant/Temporary Healing (EP) Abutment systems, is substantially equivalent to cases indicated for the use of implants distributed by the Straumann Company, "Non-Submerged Implant System", a single surgical stage implant system and the "Immediate-Load Implant" distributed by Sargon Enterprises, Inc. whose claims assert that the implant achieves immediate bone integration and therefore may be immediately loaded with temporary crowns, in that both systems are designed for single stage surgical procedure.

The 3i proposed single-stage surgical protocol is dissimilar from the Straumann system, in that it is a two or three component system utilizing the 3i 1 and 2 piece Temporary Healing (EP) Abutments in conjunction with the implant; whereas the Straumann implant is one-piece (w/ cover screw). Use of EP Healing Abutments improves on the Straumann system in that they offer a greater range in height and diameters, to more closely match the patient's soft tissues. The wide range of healing abutments also further assures that the coronal aspect of the implant/abutment unit can be more accurately placed at or just sub-gingivaly, affording greater protection from mastication forces. With the Straumann system the clinician must guess the height of the available soft-tissues when placing the one-piece implant. This may produce a variation in heights of the coronal aspect of the implant.

The 3i proposed single-stage surgical protocol is dissimilar from both Straumann and the Sargon system in that 3i at this time, does not recommend immediate loading under any circumstances.

15. 510(k) 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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Affairs/Quality Assurance