3i
IMPLANT INNOVATIONS, INC.

3071 Continental Drive
West Palm Beach, FL 33407
1-800-443-8166 (407) 840-2600
FAX (407) 840-2660

OCT 17 1996

K962014

OCT 18 1996

510(k) SUMMARY

PRE-STERILIZED, SINGLE USE, DISPOSABLE DRILLS, TAPS AND BURS
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:

   Bone cutting instrument and accessories.

2. COMMON/USUAL NAMES:

   Dental/Surgical Pilot Drills, Twist Drills, Round Drills, Taps, Burs, Counterbores, Countersinks, Cylinder Burs, Tri-Spade Drills, Trephine Burs, etc.

3. PROPRIETARY NAME:

   3i Single Use, Disposable drills, Taps, Burs, etc.

4. ESTABLISHMENT REGISTRATION NUMBER: 1038806

5. CLASSIFICATION:

   Bone cutting instruments and accessories, per Section 872.4120 are classified as Class II devices.

   Intraoral dental drills, per Section 872.4130 are classified as Class I devices, exempt from Pre-Market Notification.

   3i received marketing clearance for drills taps and burs on or about 04/17/89 - K891615. In this submission Surgical Drills were classified by FDA as Class I devices. These drills were constructed of Stainless Steel, were not offered pre-sterile and were reusable.

6. PERFORMANCE STANDARDS: Unknown

7. FORM:

The proposed pre-sterilized, single-use, disposable drills, taps and burs (3i UniSystem) will be of the same design as previous products but will be constructed of "High Speed Surgical Steel" per AISI M2. All 3i drills are marked at the appropriate depth lengths to assist the clinician in proper drilling and are labeled with the correct drill diameter(s). Each drill is also identified as a "3i" device.

Pre-sterilized, single use disposable drills, taps and burs will benefit both user and patient in that the material used in construction is capable of obtaining a much sharper cutting edge, providing for a more gentle surgical drilling process by improving efficiency in drilling (sharper drills = improved drilling efficiency with less trauma to remaining bone).

Pre-sterilized, single use disposable drills, taps and burs will be packaged in rigid xxxx trays offering greater protection from damage, and will be labeled as "single use, disposable". Also, the proposed pre-sterile, single use disposable drills, taps and burs will be significantly less expensive for the clinician.

8. PACKAGING/LABELING:

Packaging will consist of a rigid xxxx Copolyester rigid film tray, in single and multiple packs, sealed with foil laminate lidding and pouching material, and labeled with the following minimum information.

Catalog Number:

Description: SINGLE USE, XXXXXX DRILL (TAP, BUR, ETC.)
"Product catalog name/size, etc"

Lot Number: "sterile lot number"
"STERILE"

FOR SINGLE USE ONLY. DO NOT RE-STERILIZE/REUSE.

Cautions: Sterility not certified (guaranteed) if container or seal is opened or damaged.

"United States federal law restricts device to sale, distribution, or use by or on the order of a licensed dentist or physician".

Manufactured by: Implant Innovations, Inc
3071 Continental Drive
West Palm Beach, FL 33407 USA

Sterilization of the proposed drills, taps and burs shall be accomplished using Co60 Irradiation, at a minimum dose of 25.0 kGy (2.5 mRads), achieving a Sterility Assurance Level (SAL) of ten to the minus six.

Validation of sterilization process shall be accomplished as specified by the Association for the Advancement of Medical Instrumentation.
Irradiation sterilization shall be accomplished by an FDA registered irradiation sterilization facility.

The proposed drills, taps and burs differ from original designs in that the originals were constructed of surgical grade stainless steel, distributed non-sterile and were reusable. Sterility was accomplished by the clinician, using an "Auto" or "Chem" clave process.

9. CONTRAINDICATIONS:

Drilling for implant placement should not be undertaken in any case where remaining jaw bone is too diminished to support implants.

10. WARNINGS:

For safe and effective use of any surgical device or equipment including drills, it is strongly recommended that specialized training be undertaken since surgical techniques are highly specialized and complex procedures.

11. PRECAUTIONS:

Thorough screening of prospective surgical 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.

12. ADVERSE EFFECTS:

In dental implant surgery, improper drilling techniques or use of incorrect drills can result in loss of implant anchorage (failure to osseointegrate) or loss of the prosthesis after surgery. Lack of quantity or quality of remaining bone, infection, poor patient oral hygiene or cooperation, and generalized diseases (diabetes, etc.) are other potential causes for loss of fixture anchorage.

13. SURGICAL COMPLICATIONS:

The surgical 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.

14. SUBSTANTIAL EQUIVALENCE:

Pre-Sterilized, single use disposable drills are used for both dental and orthopedic procedures, and are manufactured/distributed by numerous manufacturers including among others:

Implant Innovations Inc. Drills and Burs. PMN: K891615;

Nobelpharma, "Branemark System Drills and Screw Taps";

Brasseler, Inc. Surgical Instruments; and,

The Anspach Effort, Inc. High Speed Drills and cutting tips for Right and Contra Angle cutter applications.

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, including drills, taps and Burs.

Endosseous Implants (including drills, taps and burs):

Failure of the implant 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, over-heating of bone by improper technique or use of dull drills, taps or burs**, 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.

---------- END ----------

William G. Conety
Regulatory Affairs