DEC - 4 1997

IMPLANT INNOVATIONS®

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K973771

510(k) SUMMARY

IMPLANT INNOVATION'S, INC. (3i) SURGICAL DRILLS, TAPS BURS w/ AMORPHOUS CARBON COATING

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.

510(k) SUBMISSION: AMORPHOUS CARBON COATING - SURGICAL DRILLS AND BURS

1. CLASSIFICATION NAME:

Amorphous Carbon coating (AC) in and by itself has no classification name. Devices it will be incorporated with are Dental/Surgical drills, burs and taps use in osteotomy preparation for placement of dental, oral/maxillofacial implants or other oral and maxillofacial osteo-surgical procedures.

2. COMMON/USUAL NAMES:

Dental/Surgical pilot drills, twist drills, round drills, taps, burs, counterbores, countersinks, tri-flute cylinder burs, tri-spade drills and trephine burs.

3. PROPRIETARY NAME:

3i Dental/Surgical Drills, Burs and Taps. NOTE: There is no proprietary marketing

names under consideration at this time for the AC drills, burs, taps. All such devices with AC coating will be appropriately identified within a proprietary name and/or description.

4. **ESTABLISHMENT REGISTRATION NUMBER**: 1038806

5. **CLASSIFICATION**:

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

Dental Hand instruments, per Section 872.4565 are classified as Class I devices and have been exempted from Pre-Market Notification requirements, if materials used in construction are the same as used prior to 05/28/76.

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

3i received marketing clearance on drills taps and burs with and without a Titanium Nitride Coating that was classified by FDA as Class I.

Dental drills used in surgical procedures to create the osteotomy for placement of dental implants may be considered "accessory devices" to the dental implant and therefore also considered Class III.

6. **PERFORMANCE STANDARDS**: Unknown

7. **FORM**:

The purpose of this submission is to request marketing clearance for all drills, taps and burs (hereinafter referred to simply as "drills") manufactured and/or distributed by 3i, with an Amorphous Carbon (AC) coating applied to the cutting surfaces of the devices. This submission is for clearance of AC as a coating for current and future drill designs.

3i currently manufactures and distributes a wide range of reusable and disposable machine, electro-polished and titanium nitride (TiN) surface finished drills for the oral/maxillofacial surgical market. Current drill designs are essentially the same as others constructed of Stainless Steel with machined, electro-polished or applied

TiN finishes. Applied TiN coatings seem to extend useful life of the drills, helps prevent corrosion and due to its bright yellow color, provides an excellent means for depth marking on the drill itself. It is the benefits of the TiN coatings that has prompted a extensive search of other similar biocompatable coatings.

Research has shown superior performance under extremely harsh conditions over machine finished, electro-polished and even TiN coatings, with use of "diamond like carbon", "amorphous diamond", "amorphous carbon" (AC) or any of a number of other similar carbon based coatings, exhibiting extreme hardness and low friction characteristics, not unlike that of natural diamond. **NOTE**: For purposes of this submission the term "amorphous carbon" (AC) will be used to identify the coating to be incorporated with 3i drills.

AC coatings provide excellent biocompatability, chemical inertness and a hermetic barrier to a wide range of products. It may be applied to metals, ceramics and some plastics, depending upon application processes used. In medical device use, due to excellent ware resistance and biocompatability, AC is applied to scalpels and other cutting devices, replacement-joint (Orthopedics) ware surfaces and other implantable parts. The very desirable aspects of AC coatings currently realized by other medical/surgical applications will also benefit dental surgical applications by helping to reduce surgical trauma and enhanced tissue release through very low coefficient of friction, that may also increase drilling efficiency, decrease drilling (chair) time and perhaps promote enhanced post-operative healing. Based on initial testing, AC coating will extend useful life of drills, increase visibility and ware resistance of depth marks and reduce possibility of corrosion.

The AC coating is black in color, provides excellent capabilities for "masking" or machining depth markings, will not corrode and is sterilizable by autoclave or chemclave, or any of the other normal manufacturing sterilization means (Ie: ETO, Co60 Irradiation, Plasma, etc.).

AC is a molecular bond of titanium, nitrogen, carbon and hydrogen, applied to the metal surfaces of the drills using a proprietary gas (vacuum) deposition process. The process produces a very hard, dense, amorphous, thin film (as opposed to the crystalline structure of natural diamond). These carbon based coatings are extremely hard and lubricous, very desirable qualities for "ware parts" and devices subjected to abrasive ware environments, such as drills and cutting tools. Extensive testing has been accomplished on AC coated cutting tools and drills, used in much harsher applications than surgical drilling. On parts and components subjected

to prolonged frictional applications under extreme conditions, the AC coating greatly improves ware characteristics compared to uncoated and TiN coated parts and components.

Specific testing has been undertaken with the AC coating to be used on 3i drills, results of which are not inconsistent with results published by several other related suppliers and applications.

ROLLING CONTACT FATIGUE TEST:

Uncoated	- 8.0 hrs
TiN/Ti Coated	- 102 hrs
AC Coated	- 120 hrs

SLIDING WARE TEST:

Results: No detectable ware after 5 hours.

TiN/Ti Coated	Coefficient of Friction: 0.110
TiN/Ti Coated	Coefficient of Friction: 0.124
AC coated	Coefficient of Friction: 0.090
AC coated	Coefficient of Friction: 0.080

SCRATCH TEST:

Critical load (in/lbs) to coating failure - 33.7 lbs

MICRO-BLAST TEST:

Time (seconds) to full coating removal: 78.1 seconds.

These tests and the results obtained demonstrate the AC coating to be superior in durability to uncoated and TiN coated steel, under conditions much more sever than will be encountered in 3i's indicated surgical applications. "Scratch" and "Blast" test results confirm the gas deposition process applies the coating such that it will not flake or chip off under normal handling and surgical use conditions.

8. INDICATIONS FOR USE:

Surgical drills, taps and burs are used in dental, oral/maxillofacial surgery for preparing the bone (osteotomy), to receive an implant(s) or other device for bone fracture repair for restorative reconstruction.

9. CONTRAINDICATIONS:

Surgical 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. LABEL/LABELING MATERIALS:

Labeling will not change from previous labeling except that the label will state "Amorphous Carbon Coated Drills (Taps) (Burs). All other required label information will be consistent with current labeling. There are no current proposed marketing materials planned for the AC coating on 3i drills.

15. SUBSTANTIAL EQUIVALENCE:

The proposed drills burs and taps with the AC coating are substantially equivalent to currently market 3i drills, taps and burs with either a polished or TiN coating, in that the basic design and all indications for use have not changed. Though the material used to coat the drills , burs and taps is different in composition from the original coating (TiN), it is a recognized surface treatment for Orthopedic implant appliances as well as other medical/surgical devices. The safety and efficacy of AC coatings is well documented in literature and marketing materials by others in the industry. While there are some indications of clinical benefits with AC coated surgical cutting devices and 3i's initial testing has confirmed improvements in durability, there are no new specific clinical, sharpness or durability claims at this time regarding AC coated drills.

The only difference between the proposed AC drills and previous drills is the inclusion of the AC surface coating.

16. 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 surgical use of all associated 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 maxillar 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

..... END SUMMARY.....

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 1997

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

Re: K973771
Trade Name: Dental/Surgical Drills, Burs, Taps
Regulatory Class: III
Product Code: DZE
Dated: September 30, 1997
Received: October 2, 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

510(k) Number: K Page 1 of 1

Device Name: Surgical drills, burs and taps w/Amorphous Carbon Coating.

INDICATIONS FOR USE:

Surgical drills, taps and burs are used in dental, oral/maxillofacial surgery for preparing the bone (osteotomy), to receive an implant(s) or other device for bone fracture repair for restorative reconstruction. Trephine burs are used harvest bone material for autologous bone grafting procedures and to remove fractured surgical and implantable devices from the bone.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973721

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