Exhibit 07
510(k) Summary

IMPLANT INNOVATIONS®

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(561) 776-6700

510(k) SUMMARY

510(k) SUBMISSION: ORTHODONTIC ABUTMENT - For use with 3i Endosseous Dental Implant System in Orthodontic applications

To the Requestor:

Information contained in this summary is taken directly from the original Pre-Market Notification [510(k)], submission, provided the United States Food and Drug Administration. No information required by law (regulation), or information regarding safety or efficacy has knowingly been deleted or significantly altered from that submission, for this summary.

01. BACKGROUND INFORMATION:

It is well known, based on a large volume of published literature, that dental implants have been and are commonly and successfully used in orthodontic applications as anchors for abutment and fixation of orthodontic appliances. Use of dental implants in orthodontic applications, provides a firm anchor, for fixation and support of orthodontic appliances. Dental implants will resist orthodontic forces for adequate periods of time to accomplish orthodontic objectives after which, they may be used in conventional implant supported restorations. Use of dental implants in orthodontic applications is reported to eliminate the need for orthodontic headgear in many cases. A search of available literature provides clear evidence that dental implants and a wide variety of "modified " abutment components have been routinely used in orthodontic use with very predictable results.

When used in orthodontics, a standard, conical, temporary healing abutment,

abutment post, or any of a wide variety of other currently available abutments are used with the implant(s). They are modified (surface roughened) by the clinician, to promote adhesion attachment of orthodontic brackets (appliances) and attached to the implant by conventional surgical means. The orthodontic wires and/or other appliances are attached (epoxy) to these modified abutments. Upon completion of the orthodontic treatment, the abutments (and orthodontic appliances) are removed and the implant removed, "buried" or restored using conventional permanent abutment and restorative devices.

02. CLASSIFICATION NAME:

Endosseous Dental Implants (and abutments)

03. COMMON/USUAL NAMES:

Dental implants, standard/self-tapping screw-type implants, TPS and HA cylinder implants, "Osseotite" implants, standard, temporary healing abutments, abutment posts and/or any of a variety of abutment and restorative components.

04. PROPRIETARY NAME:

3i Orthodontic Abutment, "Orthobutment" (proposed).

05. ESTABLISHMENT REGISTRATION NUMBER: 1038806

06. CLASSIFICATION:

Endosseous dental implants are classified per CFR 21, Part 872.3640, as Class III devices. Date PMA or "notice of completion of a PDP is required". No effective date has been established of the requirement for premarket approval.

07. PERFORMANCE STANDARDS: None or unknown

08. FORM:

The 3i orthodontic abutment is a commercially pure titanium abutment cylinder and screw, very similar in design to 3i's "Standard" or "Two Piece Temporary Healing Abutment". The 3i orthodontic abutment" is designed specifically for

cement (epoxy) retention of an orthodontic bracket or appliance and has a 360 degree portion of the abutment cylinder plasma sprayed (TPS) with commercially pure titanium, applied by the same means and to similar specifications as 3i's TPS cylinder implants.

The 3i orthodontic abutment will be distributed cleaned but non-sterile and will be packaged in an autoclavable, heat-sealed pouch (as other 3i abutment and restorative components.

The 3i orthodontic abutment" eliminates need for modification of other types of abutments, and provides a consistent abutment design for orthodontic treatment. It is simply screwed into the integrated implant, without further preparation (with exception of sterilization by dry heat or autoclave). The pre-roughened (Titanium Plasma Sprayed) surface provides an optimum surface for epoxy adhesion attachment of orthodontic brackets.3i's orthodontic abutment may be used with any 3i endosseous dental implant of corresponding diameter and size.

The 3i implant and implant systems do not change in any form for orthodontic application or use of the orthodontic abutment.

09. LABEL/LABELING MATERIALS:

Product labeling, instructions for use and promotional materials have yet to be completed. Labeling and instructions for use will follow the same format as current materials, containing at a minimum:

Product Catalog Number
Product name, nomenclature and relevant sizes
Product lot number
3i address and phone numbers

The 3i implant instructions for use will be revised from:

"Indications for use: The 3i **Implant System** is designed for use in dental implant surgery. A successfully oseointegrated implant will achieve a firm and direct connection between the living bone and the surface of the titanium implant when surgically implanted under controlled conditions, per well known clinical studies."

To: "The 3i **Implant System** is designed for placement in alveolar bone for dental implant treatment of edentulism and orthodontic anchorage for tooth movement and re-positioning prior to implant restoration. A successfully oseointegrated implant will achieve a firm and direct connection between living bone and surface of the implant when surgically implanted under controlled conditions, per well established clinical practices" (or similar wording).

10. INDICATIONS FOR USE:

The 3i orthodontic abutment with 3i's endosseous dental implant system is (are) indicated for use in orthodontic procedures, in which prior edentulism permits implantation of a root form implant into jaw arches (alveolar bone), as an anchor for fixation and abutment (support) of an orthodontic appliance.

Upon completion of orthodontic treatment, the orthodontic abutment may be removed and replaced with a conventional 3i restorative abutment device.

11. CONTRAINDICATIONS FOR USE:

Orthodontic abutment: No known (reported) or anticipated contraindications in use of the abutment when used with a 3i implant that has achieved integration in alveolar bone. The 3i orthodontic abutment is not indicated for use in implants placed in locations other than the alveolar ridges.

Implant related 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, poor oral hygiene, heavy smoking or tobacco abuse, or medical conditions such as blood disorders, infection(s), vascular impairment at surgical site, uncontrolled diabetes, heavy smoking or tobacco abuse, drug or alcohol abuse, chronic high dose steroid therapy, medical conditions such as blood clotting disorders, current or ongoing anticoagulant therapy, metabolic bone disease or other metabolic or systemic disorders which may adversely affect bone or wound healing or cases in which the available bone is too diminished to provide adequate width or height to adequately hold implants and restorative appliances.

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. For orthodontic treatment, placement of 3i implants into sites other than alveolar ridges is not recommend.

13. PRECAUTIONS:

Thorough screening of prospective implant candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, parodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT Scans and tomogram may also be beneficial.

14. ADVERSE EFFECTS:

Orthodontic abutment: No known (reported) or anticipated 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:

Orthodontic abutment: No known or anticipated 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. SUBSTANTIAL EQUIVALENCE:

The 3i orthodontic abutment is substantially equivalent in design and materials to 3i's two-piece, temporary healing abutments (K934126), designed for temporary placement on a 3i implant to form and contour gingival tissues, for more natural "emergence profile", during the post-implant (or abutment) placement healing phase.

The 3i orthodontic abutment differs only slightly in physical design and incorporates a TPS surface to provide roughness for improved cement (epoxy) retention. The orthodontic abutment differs in "indications for use" from permanent abutment posts in that it is designed specifically for cemented orthodontic appliances, to move or realign natural dentition. Upon completion of the orthodontic procedure, the abutment is removed and replaced with a permanent abutment and prosthetic appliance.

17. PRE-MARKET NOTIFICATION CLASS III CERTIFICATION AND SUMMERY FOR SUBMISSION:

I certify I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and effectiveness problems reported in use of endosseous dental implant systems, including abutment systems and orthodontic use of implants and abutments.

No specific reports were found, of adverse safety or effectiveness with endosseous dental implants and/or abutments used in orthodontic applications.

Failure of the implant to integrate or loss of integration can be caused by improper patient selection (patients with systemic diseases which affect bone physiology, patients with habits such as bruxing, 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.

_____ end _____

William G. Conety
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1998

Mr. William G. Conety
Regulatory Affairs
3i® Implant Innovations
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K980083
Trade Name: 3i® Orthodontic Abutment, Orthobutment
Regulatory Class: III
Product Code: DZE
Dated: December 31, 1997
Received: January 9, 1998

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

Device Name: **Orthodontic Abutment** for use with 3i Endosseous Dental Implants in Orthodontic Applications

INDICATIONS FOR USE:

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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 K980083

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