IMPLANT INNOVATIONS®

DEC 23 1997

4555 Riverside Drive
Palm Beach Gardens, FL 33410
1-800-443-8166
(561) 776-6700

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION TO SUPPORT A DETERMINATION OF SUBSTANTIAL EQUIVALENCE OF IMPLANT INNOVATION'S "BIORESORBABLE FIXATION TACK".

510(k) SUBMISSION: BIORESORBABLE * FIXATION TACK

(*) Bioresorbable refers to solid polymeric materials / devices that can degrade and further resorb in vivo and are eliminated through natural pathways either because of simple filtration of degradation byproducts or after metabolization. (1)

1. BACKGROUND:

In past years there has been extensive work published on the use of bone filling, grafting and augmentation materials and techniques. Many of these procedures, generally referred to as "Guided Bone Regeneration" (GBR) or "Guided Tissue Regeneration (GTR), have been used in conjunction with dental restorative procedures using endosseous dental implants. It is not uncommon for a clinician to develop a ridge of sufficient height and/or width (GBR), in those patients who otherwise may be contraindicated for dental implant treatment, due to a lack of adequate bone. GBR is also common treatment for repairing bony defects and to fill the sockets in and around implants placed in fresh extraction sites. In nearly all of these procedures, it is necessary to guide the bone regeneration process by providing an adequate regenerative space with a stable osseous base, free of connective tissue and epithelial cells and a blood supply emanating exclusively from the bony base. This regenerative space may be constructed from components of one or more of the various bone plate/screw systems currently available, including 3i's Osseous Fixation System and any of a variety of resorbable or non-resorbable membranes and lamellar bone grafts. These are used to protect the GBR site from epithelial tissue invasion. With the use of unattached, unsecured membranes, micro- movement can cause scar tissue formation under the membrane, instead of bone. Also soft tissue (epithelial) and bacteria may invade the GBR site from around the margins of the unsecured membrane. Therefore, it is standard practice to use bone plates, screws, tacks or other forms of fixation to attach and/or support the membranes over the GBR site or framework. One drawback with use of metal screws, tacks, pins, plates, etc. is that a second surgical procedure is required to remove the supporting or

fixation hardware. A solution to this problem has been the development of Bioresorbable retentive/fixation devices, using a variety of biocompatable materials including variations of homopolymers of polyglycolide, polylactide, or copolymers thereof. A review of literature has identified a variety of devices and material variations used for years in general surgical applications (sutures), and plates, screws, pins, wires and other fixation devices used in orthopedic and craniomaxillofacial fixation applications with predictable outcomes and proven successes.

Due to widespread, clinically accepted GBR/GTR procedures using any of a variety of bone grafting/augmentation materials and bioresorbable and/or non-bioresorbable membranes and use of numerous bioresorbable bone, ligament and other tissue retentive devices, 3i is proposing to develop for distribution, a similar Bioresorbable fixation device (Tack) to secure membranes for GBR procedures in oral and maxillofacial applications. There is good clinical acceptance of such devices in that, when used with non-resorbable membranes, a second surgical procedure, though still required to remove the membrane, may be simplified by minimizing the need for full releasing incisions necessary to expose the metal retaining/fixation tacks for removal of the membrane. With bioresorbable tacks, there is no need to search for retaining hardware and in some cases it has been reported that a simple crestial incision is all that is required to expose the membrane for removal. With bioresorbable tacks, bone healing is complete at membrane removal, there are no screw holes to fill and heal. In addition, the very serious potential for dropped screws or other hardware and possible aspiration by the patient, is also significantly reduced.

When bioresorbable fixation is used with bioresorbable membranes (IE: Gore "Resolut") or other biomaterial grafts, there is no second surgical procedure for removing membrane or fixation devices. In addition to benefits described above this reduces overall patient discomfort and reduces further the ever present possibility for introduction of infection. Use of such devices has been reported to actually shorten treatment times and subsequent overall costs to the patient.

GBR procedures with use of membranes and/or bone grafting materials is an accepted treatment methodology and the clinical benefits from an adequately secured membrane to the bone during initial healing phases has been well documented. Numerous variations of bioresorbable materials have been used by manufacturers over the years in implantable, fixation devices with great successes: Bioresorbable sutures; bone and ligament fixation pins, screws

and wires, and bone plate and screw systems are on the market and widely used.

THEREFORE: 3i proposes to utilize current biomaterial technology to develop a Bioresorbable Fixation Tack for oral/maxillofacial membrane fixation.

01. **CLASSIFICATION NAME**: Intraosseous Fixation Screw or Wire

02. **COMMON/USUAL NAMES**: Bone nail, screw, tack, wire, etc.

03. **PROPRIETARY NAME**: 3i Bioresorbable Fixation Tack

04. **ESTABLISHMENT REGISTRATION NUMBER**: 1038806

05. **CLASSIFICATION**: Class II

Current bone/membrane screw and tack designed fixation devices and absorbable tissue fixation devices are Class II devices. Therefore, it is not inconsistent for 3i's proposed Bioresorbable Fixation Tack to also be Class II.

06. **PERFORMANCE STANDARDS**: Unknown/Unestablished

07. **LABEL/LABELING MATERIALS**:

Label/labeling and marketing materials have not been developed at this time.

08. **FORM**:

The device will be manufactured from a well known copolymer. This material was selected because of its biocompatibility and proven metabolic pathway through which it is metabolized and eliminated from the body. Also, because alone or as copolymers, the materials can be adjusted to provide appropriate bioresorbtion timing for a GBR/GTR device.

NOTE: Biodegradation times vary depending on implant surface area, porosity and molecular weight.

The 3i fixation tack is a copolymer. Its molecular weight and copolymer ratio is based on current and predicate device materials and through extensive literature review. The composition resorbs slowly, providing 4 week structural integrity

with adequate structural breakdown and fixation capabilities by 5 to 8 months.

The 3i Bioresorbable Fixation Tack is approximately .050 inch in diameter and .17 inch long. Small enough to effectively stabilize a membrane for an approximate 30 day period and be non-retentive by five to eight months.

The 3i Bioresorbable Fixation Tack is designed for membrane fixation in Guided Bone Regeneration (GBR) procedures and/or where other oral/maxillofacial clinical requirements necessitate use of bioresorbable or nonresorbable type membranes. The 3i Bioresorbable Fixation Tack is designed to maintain 50% of its original strength and retention capability structure through one month in actual use and effectively non-retentive at five to eight months.

The "Tack" is designed so that it may be pushed/tapped into a pre-drilled site by hand or by using a small surgical mallet, available from numerous device manufacturers including 3i.

The 3i Bioresorbable Fixation Tack may be distributed as individual devices, packaged in semi-rigid trays with moisture proof foil lids and presterilized to an SAL of 10^{-6}. Validation is accomplished by Sterilization is accomplished by an FDA registered irradiation sterilization facility with validation to applicable Haronized Standards.

Packaged tacks may also be included in "convenience kits" containing a variety of site preparation and insertion tools and accessories

09. **BASIC DIRECTIONS FOR USE**:

The 3i Fixation Tack system is used in conjunction with commercially available guided tissue regeneration membrane systems. Surgically, the implantation site for the membrane is prepared following the membrane manufacturer's directions for use. Remove the tray lid and deliver the Bioresorbable Tacks to the sterile field. Once the membrane is properly positioned over the bone defect area, and with desired regeneration space maintained, hold the membrane with the Membrane Holder/Drill Guide and drill at slow speed a 1.0 mm diameter hole approximately perpendicular to the plane of the membrane, through the membrane into the bone. Exercise care while drilling. The 1.0 mm drill is delicate and excessive forces or angular pressures may cause the drill to fracture. Allow the drill to do the work, applying only minimal force.

Using the appropriate Seating Instrument, aseptically pick-up a tack by engaging tack head with instrument tip and pressing firmly. The tack will seat within the instrument tip. Deliver the tack to the drilled hole. Using the membrane holder to maintain the membrane/drilled hole position, insert the tack through the membrane and into the hole. Firmly seat tack by pushing it straight into the hole. Avoid excessive lateral forces as the tack can fracture.

In cancellous or "soft bone", the tack may simply be pushed by hand into the drilled hole, to full seating depth.

In cortico-cancellous, cortical or "hard" bone, the Tack may require gentle tapping with a surgical mallet to be fully seated.

Repeat this process as required to achieve desired membrane stabilization.

The 3i Bioresorbable Fixation Tacks are designed to be resorbed by the body and do not require removal when the GBR procedure is complete.

10. **SUBSTANTIAL EQUIVALENCE**:

The 3i Bioresorbable Fixation Tack is substantially equivalent to other similar devices manufactured and/or distributed by, among others:

Instrument Makar, Inc. "Biologically Quiet Screw"
W. Lorenz "LactoSorb Resorbable Craniomaxillofacial Fixation"
WL Gore & Associates "Resolut" Membrane

OTHER SIMILAR DEVICES:

Linvatec Corporation " Bio-Anchor"
Mitek "GLS"

in that they are constructed of similar materials and indicated applications for use does not significantly differ except in location for use. The 3i Fixation Tack is indicated for Oral/Maxillofacial use for membrane fixation.3i's Bioresorbable Fixation Tack design, while slightly different from other bone, ligament, bone and tissue fixation devices, such as screws, pins, staples and sutures, is basically equivalent in design, in that its use application does not substantially differ. It is used to secure a membrane onto bone in non-significant load bearing situations.

It is intended to provide retentive capabilities for a minimum of 30 days and be devoid of structural integrity by 5 to 8 months.

11. **INDICATIONS FOR USE**:

The 3i Bioresorbable Fixation Tack is a membrane fixation device used in oral/maxillofacial surgical procedures for stabilizing membranes in GBR/GTR procedures or in other clinical situations that require membrane use/fixation. It may be used in conjunction with commercially available GBR membranes. IE: W.L. Gore & Associates "Resolut" or "Gore-Tex".

12. **CONTRAINDICATIONS**:

There are no known contraindications with use of Bioresorbable Fixation Tack however, there may be a remote possibility for allergic reaction to materials containing polylactide/lactic acid or glycolide/glycolic acids. Known contraindications associated with GBR/GTR procedures and/or dental implant treatment include (but are not limited to) infection(s), insufficient available bone or bone of poor quality, vascular impairment at surgical site, poor oral hygiene, 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 GBR appliances or implant(s).

13. **WARNINGS**:

It is strongly recommended that the instructions for use provided by the manufacturers of membranes, fixation devices and where applicable dental implant and restorative devices be read, understood and followed prior to undertaking any periodontal treatment involving the use of such devices.

The 3i Bioresorbable Fixation Tack is provided presterilized. Maintain sterile integrity until actual placement. Do not resterilize the device.

Membranes should not be used and affixed with 3i Bioresorbable Tacks in situations where there are defects with severe horizontal bone loss and with little remaining periodontal ligament and cementum or defects that do not allow for

creation and maintenance of a space that exhibits characteristics which may reduce the amount of regeneration clinically required. Clinicians must carefully consider the therapeutic benefit of such treatment before undertaking. Clinical judgement must be used in the selection of patients for GBR/GTR treatment, selection of the type and form of membrane and for postoperative treatment.

For safe and effective use of the various membranes and associated treatment methodologies, membrane fixation devices and dental implants and restorative devices, it is strongly suggested that specialized training be undertaken since the surgical techniques required to properly utilize these devices and procedures are highly specialized and complex. Improper patient selection and technique can cause or contribute to case failure with possible loss of supporting bone.

14. **PRECAUTIONS**:

Thorough screening of prospective implant candidates must be performed. There are patients who have medical conditions which put them at increased risk for complications following periodontal surgery. Patients with a heart valve or other prosthetic device, heart valve defect (i.e., heart murmur, prolapsed mitral valve, history of rheumatic heart disease, etc.) or uncontrollable diabetes are specific examples. The materials used in the 3i Bioresorbable Tack have not been tested in patients with a history of connective tissue disease or steriod use either at the time of treatment or for a one year period prior to treatment. Because there is no information on these types of patients, the clinician should assess all risks and benefits for these patients and consider consulting with the patient's physician prior to treatment.

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 tomograph may also be beneficial.

Preoperative treatment may include antibiotic therapy at clinician's discretion. As with any surgical procedure, careful post-operative management is important for optimal healing, including oral hygiene maintenance, plaque control, adequate flossing and brushing instructions and close patient monitoring and professional prophylaxis (no pumice with use of membranes) at lease every other week for the first eight weeks.

Postsurgical exposure of secured (or unsecured) membranes may occur and should be anticipated. The situation should be monitored but should not interfere with the GBR process.

3i's Bioresobable Fixation Tack is resorbed by the body and does not need to be removed after periodontal healing has occurred.

In the event of tissue inflammation or evidence of infection, and at the clinician's discretion, both the membrane and 3i fixation tracks may be removed. Both the 3i Bioresorbable Tack and some bioabsorbable membranes are designed to be hydrolyzed during bioresorbtion (absorption) and will lose structural integrity over time. Removal of the material may require curettage and should be accompanied by thorough flushing with a sterile saline solution.

NOTE: Always follow "instructions for use" specified by membrane manufacturer. 3i Bioresorbable Tacks are designed to maintain structural integrity and membrane retention for one month and to loss structural integrity and retentive capabilities by six to eight months. Do not probe membrane sites for at least six months after GBR implantation.

15. **ADVERSE EFFECTS**:

Possible complications with any periodontal surgery include thermal sensitivity, gingival recession, flap sloughing, resorption or ankylosis of a treated root, some loss of crestal bone height, perforation or abscess formation, infection, pain, gingival irregularities, and complications associated with the use of anesthesia.

Depending on the type and severity of the complication, as judged by the clinician, membranes and support or fixation devices may require removal and/or antibiotic therapy.

Loss of implant anchorage (failure to osseointegrate) and loss of the prosthesis are possible occurrences after implant/restoration placement procedures.

16. **SURGICAL COMPLICATIONS**:

Periodontal surgery that involves GBR procedures and dental implants 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.

_____ end _____

William G. Conety
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

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

Re: K972480
Trade Name: 3I Bioresorbable Fixation Tack
Regulatory Class: II
Product Code: DZL
Dated: September 29, 1997
Received: September 30, 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

IMPLANT INNOVATIONS®

DEC 23 1997

4555 Riverside Drive
Palm Beach Gardens, FL 33410
1-800-443-8166
(561) 776-6700

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION TO SUPPORT A DETERMINATION OF SUBSTANTIAL EQUIVALENCE OF IMPLANT INNOVATION'S "BIORESORBABLE FIXATION TACK".

510(k) SUBMISSION: BIORESORBABLE * FIXATION TACK

(*) Bioresorbable refers to solid polymeric materials / devices that can degrade and further resorb in vivo and are eliminated through natural pathways either because of simple filtration of degradation byproducts or after metabolization. (1)

1. BACKGROUND:

In past years there has been extensive work published on the use of bone filling, grafting and augmentation materials and techniques. Many of these procedures, generally referred to as "Guided Bone Regeneration" (GBR) or "Guided Tissue Regeneration (GTR), have been used in conjunction with dental restorative procedures using endosseous dental implants. It is not uncommon for a clinician to develop a ridge of sufficient height and/or width (GBR), in those patients who otherwise may be contraindicated for dental implant treatment, due to a lack of adequate bone. GBR is also common treatment for repairing bony defects and to fill the sockets in and around implants placed in fresh extraction sites. In nearly all of these procedures, it is necessary to guide the bone regeneration process by providing an adequate regenerative space with a stable osseous base, free of connective tissue and epithelial cells and a blood supply emanating exclusively from the bony base. This regenerative space may be constructed from components of one or more of the various bone plate/screw systems currently available, including 3i's Osseous Fixation System and any of a variety of resorbable or non-resorbable membranes and lamellar bone grafts. These are used to protect the GBR site from epithelial tissue invasion. With the use of unattached, unsecured membranes, micro- movement can cause scar tissue formation under the membrane, instead of bone. Also soft tissue (epithelial) and bacteria may invade the GBR site from around the margins of the unsecured membrane. Therefore, it is standard practice to use bone plates, screws, tacks or other forms of fixation to attach and/or support the membranes over the GBR site or framework. One drawback with use of metal screws, tacks, pins, plates, etc. is that a second surgical procedure is required to remove the supporting or

fixation hardware. A solution to this problem has been the development of Bioresorbable retentive/fixation devices, using a variety of biocompatable materials including variations of homopolymers of polyglycolide, polylactide, or copolymers thereof. A review of literature has identified a variety of devices and material variations used for years in general surgical applications (sutures), and plates, screws, pins, wires and other fixation devices used in orthopedic and craniomaxillofacial fixation applications with predictable outcomes and proven successes.

Due to widespread, clinically accepted GBR/GTR procedures using any of a variety of bone grafting/augmentation materials and bioresorbable and/or non-bioresorbable membranes and use of numerous bioresorbable bone, ligament and other tissue retentive devices, 3i is proposing to develop for distribution, a similar Bioresorbable fixation device (Tack) to secure membranes for GBR procedures in oral and maxillofacial applications. There is good clinical acceptance of such devices in that, when used with non-resorbable membranes, a second surgical procedure, though still required to remove the membrane, may be simplified by minimizing the need for full releasing incisions necessary to expose the metal retaining/fixation tacks for removal of the membrane. With bioresorbable tacks, there is no need to search for retaining hardware and in some cases it has been reported that a simple crestial incision is all that is required to expose the membrane for removal. With bioresorbable tacks, bone healing is complete at membrane removal, there are no screw holes to fill and heal. In addition, the very serious potential for dropped screws or other hardware and possible aspiration by the patient, is also significantly reduced.

When bioresorbable fixation is used with bioresorbable membranes (IE: Gore "Resolut") or other biomaterial grafts, there is no second surgical procedure for removing membrane or fixation devices. In addition to benefits described above this reduces overall patient discomfort and reduces further the ever present possibility for introduction of infection. Use of such devices has been reported to actually shorten treatment times and subsequent overall costs to the patient.

GBR procedures with use of membranes and/or bone grafting materials is an accepted treatment methodology and the clinical benefits from an adequately secured membrane to the bone during initial healing phases has been well documented. Numerous variations of bioresorbable materials have been used by manufacturers over the years in implantable, fixation devices with great successes: Bioresorbable sutures; bone and ligament fixation pins, screws

and wires, and bone plate and screw systems are on the market and widely used.

THEREFORE: 3i proposes to utilize current biomaterial technology to develop a Bioresorbable Fixation Tack for oral/maxillofacial membrane fixation.

01. **CLASSIFICATION NAME**: Intraosseous Fixation Screw or Wire

02. **COMMON/USUAL NAMES**: Bone nail, screw, tack, wire, etc.

03. **PROPRIETARY NAME**: 3i Bioresorbable Fixation Tack

04. **ESTABLISHMENT REGISTRATION NUMBER**: 1038806

05. **CLASSIFICATION**: Class II

Current bone/membrane screw and tack designed fixation devices and absorbable tissue fixation devices are Class II devices. Therefore, it is not inconsistent for 3i's proposed Bioresorbable Fixation Tack to also be Class II.

06. **PERFORMANCE STANDARDS**: Unknown/Unestablished

07. **LABEL/LABELING MATERIALS**:

Label/labeling and marketing materials have not been developed at this time.

08. **FORM**:

The device will be manufactured from a well known copolymer. This material was selected because of its biocompatibility and proven metabolic pathway through which it is metabolized and eliminated from the body. Also, because alone or as copolymers, the materials can be adjusted to provide appropriate bioresorbtion timing for a GBR/GTR device.

NOTE: Biodegradation times vary depending on implant surface area, porosity and molecular weight.

The 3i fixation tack is a copolymer. Its molecular weight and copolymer ratio is based on current and predicate device materials and through extensive literature review. The composition resorbs slowly, providing 4 week structural integrity

with adequate structural breakdown and fixation capabilities by 5 to 8 months.

The 3i Bioresorbable Fixation Tack is approximately .050 inch in diameter and .17 inch long. Small enough to effectively stabilize a membrane for an approximate 30 day period and be non-retentive by five to eight months.

The 3i Bioresorbable Fixation Tack is designed for membrane fixation in Guided Bone Regeneration (GBR) procedures and/or where other oral/maxillofacial clinical requirements necessitate use of bioresorbable or nonresorbable type membranes. The 3i Bioresorbable Fixation Tack is designed to maintain 50% of its original strength and retention capability structure through one month in actual use and effectively non-retentive at five to eight months.

The "Tack" is designed so that it may be pushed/tapped into a pre-drilled site by hand or by using a small surgical mallet, available from numerous device manufacturers including 3i.

The 3i Bioresorbable Fixation Tack may be distributed as individual devices, packaged in semi-rigid trays with moisture proof foil lids and presterilized to an SAL of 10^{-6}. Validation is accomplished by Sterilization is accomplished by an FDA registered irradiation sterilization facility with validation to applicable Haronized Standards.

Packaged tacks may also be included in "convenience kits" containing a variety of site preparation and insertion tools and accessories

09. **BASIC DIRECTIONS FOR USE**:

The 3i Fixation Tack system is used in conjunction with commercially available guided tissue regeneration membrane systems. Surgically, the implantation site for the membrane is prepared following the membrane manufacturer's directions for use. Remove the tray lid and deliver the Bioresorbable Tacks to the sterile field. Once the membrane is properly positioned over the bone defect area, and with desired regeneration space maintained, hold the membrane with the Membrane Holder/Drill Guide and drill at slow speed a 1.0 mm diameter hole approximately perpendicular to the plane of the membrane, through the membrane into the bone. Exercise care while drilling. The 1.0 mm drill is delicate and excessive forces or angular pressures may cause the drill to fracture. Allow the drill to do the work, applying only minimal force.

Using the appropriate Seating Instrument, aseptically pick-up a tack by engaging tack head with instrument tip and pressing firmly. The tack will seat within the instrument tip. Deliver the tack to the drilled hole. Using the membrane holder to maintain the membrane/drilled hole position, insert the tack through the membrane and into the hole. Firmly seat tack by pushing it straight into the hole. Avoid excessive lateral forces as the tack can fracture.

In cancellous or "soft bone", the tack may simply be pushed by hand into the drilled hole, to full seating depth.

In cortico-cancellous, cortical or "hard" bone, the Tack may require gentle tapping with a surgical mallet to be fully seated.

Repeat this process as required to achieve desired membrane stabilization.

The 3i Bioresorbable Fixation Tacks are designed to be resorbed by the body and do not require removal when the GBR procedure is complete.

10. **SUBSTANTIAL EQUIVALENCE**:

The 3i Bioresorbable Fixation Tack is substantially equivalent to other similar devices manufactured and/or distributed by, among others:

Instrument Makar, Inc. "Biologically Quiet Screw"
W. Lorenz "LactoSorb Resorbable Craniomaxillofacial Fixation"
WL Gore & Associates "Resolut" Membrane

OTHER SIMILAR DEVICES:

Linvatec Corporation " Bio-Anchor"
Mitek "GLS"

in that they are constructed of similar materials and indicated applications for use does not significantly differ except in location for use. The 3i Fixation Tack is indicated for Oral/Maxillofacial use for membrane fixation.3i's Bioresorbable Fixation Tack design, while slightly different from other bone, ligament, bone and tissue fixation devices, such as screws, pins, staples and sutures, is basically equivalent in design, in that its use application does not substantially differ. It is used to secure a membrane onto bone in non-significant load bearing situations.

It is intended to provide retentive capabilities for a minimum of 30 days and be devoid of structural integrity by 5 to 8 months.

11. **INDICATIONS FOR USE**:

The 3i Bioresorbable Fixation Tack is a membrane fixation device used in oral/maxillofacial surgical procedures for stabilizing membranes in GBR/GTR procedures or in other clinical situations that require membrane use/fixation. It may be used in conjunction with commercially available GBR membranes. IE: W.L. Gore & Associates "Resolut" or "Gore-Tex".

12. **CONTRAINDICATIONS**:

There are no known contraindications with use of Bioresorbable Fixation Tack however, there may be a remote possibility for allergic reaction to materials containing polylactide/lactic acid or glycolide/glycolic acids. Known contraindications associated with GBR/GTR procedures and/or dental implant treatment include (but are not limited to) infection(s), insufficient available bone or bone of poor quality, vascular impairment at surgical site, poor oral hygiene, 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 GBR appliances or implant(s).

13. **WARNINGS**:

It is strongly recommended that the instructions for use provided by the manufacturers of membranes, fixation devices and where applicable dental implant and restorative devices be read, understood and followed prior to undertaking any periodontal treatment involving the use of such devices.

The 3i Bioresorbable Fixation Tack is provided presterilized. Maintain sterile integrity until actual placement. Do not resterilize the device.

Membranes should not be used and affixed with 3i Bioresorbable Tacks in situations where there are defects with severe horizontal bone loss and with little remaining periodontal ligament and cementum or defects that do not allow for

creation and maintenance of a space that exhibits characteristics which may reduce the amount of regeneration clinically required. Clinicians must carefully consider the therapeutic benefit of such treatment before undertaking. Clinical judgement must be used in the selection of patients for GBR/GTR treatment, selection of the type and form of membrane and for postoperative treatment.

For safe and effective use of the various membranes and associated treatment methodologies, membrane fixation devices and dental implants and restorative devices, it is strongly suggested that specialized training be undertaken since the surgical techniques required to properly utilize these devices and procedures are highly specialized and complex. Improper patient selection and technique can cause or contribute to case failure with possible loss of supporting bone.

14. **PRECAUTIONS**:

Thorough screening of prospective implant candidates must be performed. There are patients who have medical conditions which put them at increased risk for complications following periodontal surgery. Patients with a heart valve or other prosthetic device, heart valve defect (i.e., heart murmur, prolapsed mitral valve, history of rheumatic heart disease, etc.) or uncontrollable diabetes are specific examples. The materials used in the 3i Bioresorbable Tack have not been tested in patients with a history of connective tissue disease or steriod use either at the time of treatment or for a one year period prior to treatment. Because there is no information on these types of patients, the clinician should assess all risks and benefits for these patients and consider consulting with the patient's physician prior to treatment.

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 tomograph may also be beneficial.

Preoperative treatment may include antibiotic therapy at clinician's discretion. As with any surgical procedure, careful post-operative management is important for optimal healing, including oral hygiene maintenance, plaque control, adequate flossing and brushing instructions and close patient monitoring and professional prophylaxis (no pumice with use of membranes) at lease every other week for the first eight weeks.

Postsurgical exposure of secured (or unsecured) membranes may occur and should be anticipated. The situation should be monitored but should not interfere with the GBR process.

3i's Bioresobable Fixation Tack is resorbed by the body and does not need to be removed after periodontal healing has occurred.

In the event of tissue inflammation or evidence of infection, and at the clinician's discretion, both the membrane and 3i fixation tracks may be removed. Both the 3i Bioresorbable Tack and some bioabsorbable membranes are designed to be hydrolyzed during bioresorbtion (absorption) and will lose structural integrity over time. Removal of the material may require curettage and should be accompanied by thorough flushing with a sterile saline solution.

NOTE: Always follow "instructions for use" specified by membrane manufacturer. 3i Bioresorbable Tacks are designed to maintain structural integrity and membrane retention for one month and to loss structural integrity and retentive capabilities by six to eight months. Do not probe membrane sites for at least six months after GBR implantation.

15. **ADVERSE EFFECTS**:

Possible complications with any periodontal surgery include thermal sensitivity, gingival recession, flap sloughing, resorption or ankylosis of a treated root, some loss of crestal bone height, perforation or abscess formation, infection, pain, gingival irregularities, and complications associated with the use of anesthesia.

Depending on the type and severity of the complication, as judged by the clinician, membranes and support or fixation devices may require removal and/or antibiotic therapy.

Loss of implant anchorage (failure to osseointegrate) and loss of the prosthesis are possible occurrences after implant/restoration placement procedures.

16. **SURGICAL COMPLICATIONS**:

Periodontal surgery that involves GBR procedures and dental implants 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.

_____ end _____

William G. Conety
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

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

Re: K972480
Trade Name: 3I Bioresorbable Fixation Tack
Regulatory Class: II
Product Code: DZL
Dated: September 29, 1997
Received: September 30, 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

IMPLANT INNOVATIONS®

4555 Riverside Drive
Palm Beach Gardens, FL 33410
1-800-443-8166
(561) 776-6700

INDICATIONS FOR USE

510(k) Number: K972480

Device Name: Bioresorbable Fixation Tack

INDICATIONS FOR USE:

The 3i Bioresorbable Fixation Tack is indicated for use as a means of membrane fixation in Guided Bone Regeneration (GBR) procedures.

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 K972480

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