



a.k983347

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## EXHIBIT 09 510(k) SUMMARY

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 pertinent information regarding safety or efficacy has been knowingly or purposely deleted from that submission, for this summary.

**William G. Conety**  
**Regulatory Affairs**

### **510(k) SUBMISSION: OSSEOTITE® Dental Implant System:**

Performance claim: Reduced time from implant placement to clinical evaluation for prosthetic loading with **OSSEOTITE®** implants.

**CLASSIFICATION NAME:** Endosseous Dental Implant

**COMMON/USUAL NAMES:** Threaded/screw type dental implants

**PROPRIETARY NAME:** **OSSEOTITE®** Dental Implants

**CLASSIFICATION:** Endosseous implants, per 872.3640 are class III devices. Date PMA or notice of Completion of a PDP is required but no effective date has yet been established for the requirements for pre-market approval.

**PERFORMANCE STANDARDS:** Unknown

**DEFINITIONS:** In this submission the following definitions apply:

**Stage-one surgery** means the surgical procedure to place an implant and healing abutment or one-stage implant with cover screw as support for a prosthetic appliance.

**Healing time** means time between placement and prosthetic application (loading).

**Adequate healing** means assessment by clinical evaluation.

**Prosthetic appliance** means provisional or permanent.

## **BACKGROUND:**

Historically, it has been reported and generally accepted that successful implant treatment requires some defined period of time for healing between implant placement and restorative procedures. Many have endorsed the position that at least three to four months healing is required for implants placed in the mandible or other sites with dense bone and five to six months for maxillary implants or where mostly soft trabecular bone is present. Since these suggested recommendations were first published, they have become *de facto* standards for dental implant treatment and for many clinicians, an integral part of their standard treatment modality. Most now understand that in addition to time, adequate healing or integration of implant to bone is also related to patient general and oral health, overall scope and complexity of the clinical/surgical procedure(s) and to some extent, the skill and experience of the implant surgeon. It is also well known and understood that even with, the best of all conditions, there are still implant treatment failures for which there seems no identifiable cause(s).

Recently there's been increase activity in performance claims relating to reduced healing times or elimination altogether of unloaded post-implant healing times and clinical studies reported to substantiate these claims. All this clinical data being reported lends some validity to suggestions that implant design, surface structure or surface features or perhaps some combination thereof, may relate or contribute in some way to a physiological phenomenon, affecting actual healing times. 3i also early on, recognized the benefits of improving overall dental implant treatment, through development of device design enhancements that simplified or otherwise improved the science of dental implantology. One of the key outcomes of this has been development of the OSSEOTITE® Implant.

## **RESEARCH AND CLINICAL TESTING OVERVIEW:**

To generate bone in direct apposition to an implant surface, the osteoblast and other

osteogenic material must migrate to and contact the implant surface. The gap between bone and implant surface must be bridged. It's reported osteoblast utilize two different methods to approach and deposit bone on an implant surface. These two methods are referred to as "Distance" and Contact Osteogenesis". In "distance osteogenesis", new bone is created and formed on the surface of existing bone; the process continuously repeated until bone healing or growth is completed or until the new bone encroaches upon the implant surface. However, "distance osteogenesis" phenomenon does not appear to completely close the gap between living bone and implant surface. When "distance osteogenesis" is the primary means of bone healing, the implant will always be partially separated from the bone by trapped connective tissue. With "contact osteogenesis", new bone is formed directly upon the implant surface. Contact osteogenesis relies on migration of osteogenic cells directly to the implant surface. Migration occurs along the fibrin network formed during blood clot resolution. However, it's been noted that any disruption of this fibrin network may result in redirection of osteoblast from the implant surface. Thus, the defined OSSEOTITE® surface morphology may explain its ability to maintain the clot or fibrin network (referred to also as ossteoconductivity).

Since market introduction, 3i has been approached by numerous academic and clinical researchers for materials and support to further evaluate the unique OsseoTite surface and its relationship to bone interface and tissue reaction. These ongoing evaluations and clinical studies indicate OSSEOTITE® surface appears to provide greater overall performance success rates when used in areas normally associated with poorer bone quality such as posterior maxilla and based on initial results, also appears to require less time to achieve adequate healing between stage one surgery and prosthetic loading. Interim results from various ongoing evaluations, animal studies and clinical trials using OSSEOTITE® implants provide additional evidence of a correlation between implant surface morphology and bone growth and possible healing abilities, clearly demonstrating an increase in resistance to countertorque extraction for OSSEOTITE® implants compared to machined surfaced implants at healing times significantly less than previously recommended in surgical manuals and Instructions for Use. From ongoing clinical trials it has also been reported that OSSEOTITE® implants appear to attain a firm attachment, integrated with new bone in significantly less time than non-OSSEOTITE® implants for consideration of prosthetic loading

#### **SUBSTANTIAL EQUIVALENCE:**

OSSEOTITE® Implants have been determined substantially equivalent in design and materials to other standard and self-tapping implants currently in commercial

distribution. Information and materials contained within this submission do not alter the Agency's original determination of substantial equivalence of OSSEOTITE®, but provides additional information to support a marketing claim of reduced stage-one healing time from four months for implants placed in the mandible or other locations with dense bone and from six months to two months regardless of mandible, maxilla or placement sites with seeming less dense or trabecular bone.

Proposed reduced healing time claims are substantially equivalent to claims made by other manufacturers that recognize implant surface area and morphology as relevant factors to faster healing, though implant designs materials may differ.

3i continues to recommend unloaded healing times.

3i does not claim specific healing times but recommends clinical evaluation for application of a prosthetic appliance at two months post stage-one surgery, provided all healing or integration criteria are met continuation of the restorative process and possible prosthetic attachment.

#### **LABEL/LABELING MATERIALS:**

Product labels will not change from those specified in original OSSEOTITE® Pre-Market notification or OSSEOTITE® Single Stage Implants. Instructions for use, promotional materials and future surgical manuals, brochures, instructions for OSSEOTITE® surfaced implants will be revised to reflect the claim for reduced healing time to consideration of prosthetic loading.

Marketing/promotional materials may be developed to include wording such as reduced healing time or similar such wording to indicate that prosthetic loading may be considered at substantially reduced time periods, from those previously recommended, when OSSEOTITE® surfaced implants are used.

Suggested new surgical manual wording: "The time elapsed between surgical implant placement and the final abutment placement is referred to as the healing or osseointegration period. The duration of the healing is dependent upon the quality of the bone at the specific site. OSSEOTITE® implants experience an accelerated healing rate due to an increase in contact osteogenesis activity. Interim results from ongoing clinical studies demonstrate OSSEOTITE® implants, when placed in accordance with good clinical practice, may be reasonably expected to achieve adequate healing (integration), two months after surgical placement and consideration

of prosthetic loading may be undertaken at that time. Healing periods can vary or be modified, depending on many factors including bone quality at implantation site and/or clinical assessment of bone density at the time of the surgical procedure. A radiographic examination after two months and prior to restoration, should be completed to confirm adequate healing (absence of radiolucency). During the healing period, the implant must remain unloaded. Extreme care must be taken to avoid pressure on or over the implant during this period. Existing prosthetic devices, if reused must be appropriately altered to protect the implant site from masticatory forces or if a temporary restoration is used, it must be designed so as to prevent functional loading of the OSSEOTITE® implant.”

### **INDICATIONS FOR USE:**

An Endosseous dental implant is indicated for surgical placement in the upper or lower jaw arches, to provide a root form means for prosthetic appliance attachment to restore a patient's chewing function. There is no change in indications for use from those specified in the original Pre-Market Notification except that with OSSEOTITE® implants, the time required to achieve adequate healing after stage one surgery for prosthetic loading consideration may be reduced to two months regardless of mandible, maxilla or placement sites with seeming less dense or trabecular bone, provided all clinical healing (integration) criteria are met for prosthetic application.

### **CONTRAINDICATIONS:**

Implants 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.

### **WARNINGS:**

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.

#### **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.

#### **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.

#### **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.

#### **PRE-MARKET NOTIFICATION CLASS III CERTIFICATION AND SUMMARY FOR SUBMISSION:**

I certify a reasonable search has been conducted of all information known or otherwise available about the types and causes of safety and/or effectiveness problems that have been reported for Endosseous Dental Implant systems, including abutment 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 (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.

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William G. Conety  
Regulatory Affairs



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 6 1999

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

Re: K983347  
Trade Name: OSSEOTITE® Dental Implant  
Regulatory Class: III  
Product Code: DZE  
Dated: September 18, 1998  
Received: September 23, 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 legally marketed predicate 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 (Pre-market 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 requirements, 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 pre-market notification submission does not affect any obligation you might have under sections 531

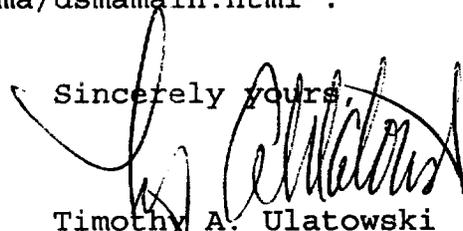
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21CFR 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/dsma/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: [REDACTED] K983347

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**Device Name:** Endosseous Dental Implant - OSSEOTITE® Dental Implant System (Original Pre-Market Notification number K935544).

**INDICATIONS FOR USE:**

An endosseous dental implant is indicated for surgical placement in the upper or lower jaw arches, to provide a root form means for prosthetic appliance attachment and to restore a patient's chewing function.

With use of OSSEOTITE® implants, the time between surgical implant placement and evaluation for prosthetic loading may be reduced from previously recommended four months (mandible) and six months (maxillary) to, two months for either mandibular or maxillary sites, when such evaluation confirms appropriate conditions for prosthetic attachment and masticatory loading.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Pinner*

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number [REDACTED] K983347

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

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