

K980549

APR 28 1998

510(k) SUMMARY

510(k) SUBMISSION: "Osseotite" Dental Implant System: "Enhanced Performance in Poor Bone"

To the Requestor:

This information is taken directly from the original Pre-Market Notification [510(k)], submission, provided to the United States Food and Drug Administration. No information regarding safety or efficacy has been deleted from that submission, for this summary.

1. **CLASSIFICATION NAME:** Endosseous Dental Implant
2. **COMMON/USUAL NAMES:** Dental implants, Screw type dental implants,
3. **PROPRIETARY NAME:** "Osseotite" Dental Implants
4. **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 .
5. **PERFORMANCE STANDARDS:** Unknown
6. **FORM:**

Screw type implant with a "Defined Surface Structure". In , the Company submitted information to support distribution clearance for a manufacturing process change, that would produce a "Defined Surface Structure (morphology) to the Company's threaded implants. This design feature, now known as "Osseotite" was cleared for commercial distribution on .

Since introduction, "Osseotite" has generated significant interest in the dental implant community. Numerous academic and clinical researchers are involved with a variety of studies to evaluate the unique "Osseotite" surface and bone interface and reaction. Prospective clinical trials are ongoing (to support Class III clinical trial requirements for Pre-market Approval).

Several studies have recently been published that present significant findings indicating the “Osseotite” surface performs overall, at least as well as other “non-Osseotite” surfaced implants and in some cases, appears to offer improved or enhanced performance in areas of the oral cavity, known (or commonly known) to have poor or poorer quality bone, as defined by Albrektsson ¹ such as the posterior maxilla.

Published studies are supported by preliminary results reported from clinical trials, using “Osseotite”. Published results of animal studies using “Osseotite” implants contained within this report, demonstrate either an increase in bone-to-surface contact or an increase in resistance to countertorque extraction for “Osseotite” compared to machined surfaced implants. In two ongoing clinical trials, It is reported that “Osseotite” implants surgically placed in areas known to have poor quality bone, have life table curves that are approximately 8.8% (% “Osseotite” vs “non-Osseotite”, machined surface implants) greater than for similar implants at 24 months. This demonstrates improvement in outcomes of implants of similar design but with different surface morphology.

7. SUBSTANTIAL EQUIVALENCE: 3i “Osseotite” Implants have been determined substantially equivalent in design and materials to 3i’s standard and self-tapping implants, the , and implant systems. Information and materials contained within this submission do not alter the Agency’s original determination of substantial equivalence of the “Osseotite” implant, but does provide adequate information to support a marketing claim of “Enhanced performance” as defined herein.

9. LABEL/LABELING MATERIALS:

Product labels will not change from those specified in the original “Osseotite” Pre-Market notification (K). Marketing materials, including claims for “Enhanced performance in poor bone”, “... poor quality bone”, or similar wording will be developed and will site, or identify means by which completed, published studies and/or ongoing clinical study results may be obtained that support these “enhanced performance” claims.

10. “OSSEOTITE” TECHNICAL REPORT:

¹ Branemark PI, Introduction to Osseointegration. In: Branemark PI, Zarb GA, Albrektsson T, editors. Tissue integrated prosthesis: Osseointegration in clinical dentistry. Chicago: Quintessence, 1985. p 202.

11. 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. A successfully Osseo-integrated implant will achieve a firm and direct connection between the living bone and the surface of the titanium or titanium alloy implant when surgically implanted under controlled conditions, per well known clinical studies.

There has been no change in the indications for use from those specified in the original Pre-Market Notification (K). This submission only provides clinical information and data to support a claim of enhanced performance in poor quality bone, using the 3i "Osseotite" Implant.

12. CONTRAINDICATIONS:

3i 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.

13. WARNINGS:

For safe and effective use of 3i implants, 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.

14. 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.

15. 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.

16. 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1998

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

Re: K980549
Trade Name: Osseotite Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: January 28, 1998
Received: January 28, 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

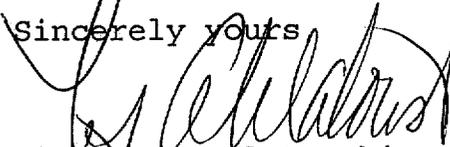
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

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Device Name: "Osseotite" Dental Implant System (Original K935544 - Process change) **Performance Claim:** "Enhanced Performance in Poor Bone"

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. This submission provides information and animal/clinical data to support a clinical performance claim of "Enhanced Performance in Poor Quality Bone".

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sandra L. Shive MS for (MSR)
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980549

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