

SEP 15 2003

K030614

510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Implant Innovations, Inc. (<i>3i</i>)
Contact Person	Mrs. Jacquelyn A. Hughes, RAC Implant Innovations, Inc. 4555 Riverside Drive Palm Beach Gardens, FL 33410 (561) 776-6819 jhughes@3implant.com
Date Prepared	June 19, 2003
Device Name	<i>3i</i> Dental Implants
Classification Names	Endosseous dental implant
Device Classification	Classification: III Classification Panels: Dental Regulation Number: 872.3640
Predicate Device(s)	<i>3i</i> Dental Implants (K860653, K874590, K935544, K950204, K955428, K972444, K983347, K014235, K022009) <i>3i</i> Abutments/Accessories K871863, K871954, K891613, K895462, K895463, K904228, K934126, K933969, K933462, K932123, K951553, K022113 Nobel Biocare Branemark System Implants (K992937, K022562) FRIADENT FRIALIT-2 Implant (K994376) Straussman ITI Implant (K984104) Dentatus MTI Modular Transitional Implants (K980620)
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act.

**Device
Description**

This 510(k) requests an expansion of the indications for use of all externally and internally hexed *3i* dental implants to include immediate loading procedures in the mandible when using a minimum of four (4) splinted implants ≥ 10 mm in length. Standard, commercially available *3i* abutments and screws can be used with *3i* dental implants in immediate loading procedures. Several new components will complement the standard line for the clinicians use as necessary in immediate occlusal loading.

**Indications for
Use**

3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, freestanding bridges and to retain overdentures.

In addition, when a minimum of 4 implants, ≥ 10 mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.

**Technological
Characteristics**

The proposed *3i* implants and accessories are identical to the currently marketed *3i* dental implants and accessories and similar in design, materials, and intended use to other legally marketed dental implant systems that are indicated for immediate loading. In addition to the standard *3i* abutments, *3i* proposes to add a single piece abutment which combines the abutment and screw into a single piece for ease of use.

**Nonclinical
Performance
Testing**

3i implants have been mechanically tested consistent with the FDA guidance document *Information Necessary for Premarket Notifications Submissions for Screw-Type Endosseous Implants* (December 9, 1996). Static Load compression testing was used to simulate biting forces placed upon the implants and Cyclic Fatigue testing simulated the chewing forces placed upon the implants. The new single piece abutment was tested for insertion torque and passed at more than five times the recommended insertion torque of 20 Ncm. The single piece abutment was also tested and passed Cyclic Fatigue criteria. Animal studies which proved early loading to be successful for *3i*'s OSSEOTITE implant systems were submitted in K983347 (cleared September 23, 1998). Subsequent data continues to provide evidence of substantial clinical success with early loading. Current practice in the field includes use in a manner described within this 510(k) with clinicians and laboratories working to achieve immediate occlusal loading in edentulous and partially edentulous patients with Types I, II and III bone.

**Clinical
Performance
Testing**

A current review of the literature suggests clinical success using immediate loading with fully and partially edentulous patients with OSSEOTITE, TPS, Ha-coated, and grit-blasted surfaces when the occlusal load is well-distributed. A few are summarized here and a bibliography may be found in Appendix 3

of the submission.

Tarnow DP, Emtiaz S, Classi A. Immediate loading of threaded implants at stage 1 surgery in edentulous arches: Ten consecutive case reports with 1 to 5 year data. *Int. J. Oral Maxillofac Implants* 1997; 12:319-324. Tarnow et al report on ten consecutive, edentulous cases comparing the use of implants manufactured by Nobel Biocare (cases 1-3 and 5-7), ITI Straumann (case 4), Astra Tech (cases 8 and 9) and *3i* Implant Innovations (case 10). Of 107 implants placed, 104 osseointegrated. For medicolegal reasons, 38 of the implants were submerged and unloaded. The three failed implants occurred in cases 2 and 3, one submerged due to an infection from an adjacent extraction site and two loaded implants due to the cemented provisional restoration being tapped off at 4 months.

Testori T, Szmukler-Moncler s, Francetti L, Del Fabbro M, Scarano A, Piattelli A, Weinstein R. Immediate loading of Osseotite implants: A case report and histologic analysis after 4 months of occlusal loading. *Int. J. Periodontics Restorative Dent.* 2001;21,5:451-459. Testori et al studied 12 Osseotite implants in the mandible of one patient of which 6 were bilaterally splinted and immediately loaded and 6 were left to heal in a submerged manner. Clinical and histologic osseointegration was confirmed for two of the immediately loaded implants by retrieval after 4 months of function. Histomorphometric evaluation revealed 78%-85% bone-to-implant contact, indicating osteogenesis and bone remodeling were not impeded by immediate loading.

Defrancq WD, Luc MDT, Rutten P. Immediate loading: Immediate loading of implants – clinical and technical procedure. *Dental Dialogue* 2002;2:246-275. Defrancq et al report successful use of an immediate loading technique in 102 procedures for both maxilla and mandible. Of 417 Osseotite implants in 68 mandible procedures only 2 were lost and only 9 of 309 Osseotite implants were lost in 34 maxilla procedures. In ten patients, implants were inserted in both the mandible and maxilla in the surgery for immediate loading.

Ibanez, JC, Jalbout, ZN. Immediate loading of Osseotite implants: Two-year results. *Implant Dentistry* 2002;11,2:128-134. Ibanez and Jalbout report 100% success in the use of 87 Osseotite implants for immediate loading in eleven patients after two-three years follow-up. Follow-up consisted of both clinical and radiographic examination which found no implant mobility or periimplant radiolucency.

Clinical reports are included in Appendix 3 for reference by Chiapasco et al, Jaffin et al, Schnitman et al, Szmukler-Moncler et al, and Balshi and Wolfinger which discuss the use of immediate loading with various competitive implants to which *3i* implants are substantially equivalent in design and materials.

Conclusion

The *3i* dental implants and accessories are substantially equivalent to the legally marketed *3i* dental implant systems, Branemark System (Nobel Biocare), FRIALIT-2, Straumann ITI and Dentatus dental implant systems.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jacquelyn A. Hughes
Director, Regulatory Affairs & Quality Assurance
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K030614
Trade/Device Name: 3I Dental Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: June 19, 2003
Received: June 20, 2003

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030614

Device Name: *3i* Dental Implants

Indications for Use:

3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, freestanding bridges and to retain overdentures.

In addition, when a minimum of 4 implants, ≥ 10 mm in length, are placed in the the mandible and splinted in the anterior region, immediate loading is indicated.

Rein Malay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K030614

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)