K 022113

SEP 1 9 2002

IMPLANT INNOVATIONS, INC.
A BIOMET COMPANY

Summary of Safety & Effectiveness

COMPANY:

Implant Innovations, Inc.
4555 Riverside Drive
Palm Beach Gardens, FL 33410

CONTACT:

Jeannette G. Dailey, RAC
Regulatory Affairs Manager
Telephone: 561-776-6913
Fax: 561-776-6852
E-mail: jdailey@3implant.com

DATE PREPARED:

June 27, 2002

NAME OF THE DEVICE:

3i Dental Accessories

CLASSIFICATION:

DZE Class III

COMMON NAME:

Endosseous Dental Accessories

PREDICATE DEVICES:

3i Dental Accessories cleared for marketing via the following premarket notifications:

- K935544 – *3i* Implants
- K952811 – *3i* Oral/Maxillofacial Bone Fixation System
- K962014 – *3i* Single Use, Disposable Drills, Taps, Burs
- K962465 – TIL313 Abutment and Retaining Screw System
- K965077 – Single Tooth Abutment System
- K992334 – Endosseous Implants and Abutments
- K012911 – *3i* Locater Abutment System
- K013570 – OSSEOTITE® Dental Implant System

DEVICE DESCRIPTION:

Dental implants are surgically inserted into the upper and/or lower jawbone and are left to heal (osseointegrate) with the bone for a period of up to six months. Upon healing and integration with the bone, the cover screw or healing abutment (if used) is removed, impressions are taken, and either a transmucosal abutment (which will later be attached to a custom prosthesis) or an emergence profile (EP) healing abutment is attached to the implant. The soft tissues are allowed to heal around the abutment forming the soft tissues to the contours of the abutment "emergence" profiling. The implant becomes the artificial root structure for a prosthetic tooth or as an abutment structure for bridge work and/or denture retention.

Implant Innovation's dental accessories are available in a wide range of sizes; and are manufactured from various materials.

This premarket notification relates to marketing previously non-sterile ***3i*** dental accessories as sterile for user convenience. The devices are packaged in sterilization-compatible packaging (heat-sealed nylon pouch) and sterilized by gamma irradiation.

There are no changes to the design, materials, or the Indications for Use for the accessories.

INDICATIONS FOR USE:

Implant Innovation, Inc., ***3i,*** Dental Implants and Accessories are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.

PERFORMANCE DATA:

The accessories were subjected to multiple exposures of gamma irradiation and analyzed for mechanical strength. An analysis of the data demonstrated there were no significant differences in the materials pre- vs. post-sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jeanette G. Dailey
Regulatory Affairs Manager
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

SEP 19 2002

Re: K022113
Trade/Device Name: *3i* Dental Implant Accessories
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: June 27, 2002
Received: June 28, 2002

Dear Ms. Dailey:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Patricia Cucciotti/for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _K022113__

Device Name: *3i* Dental Accessories

Indications for Use:

3i Dental Accessories are indicated for use in surgical and restorative applications when placing dental implants.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Susan Runco

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

510(k) Number: K022113