K012911

Summary of Safety & Effectiveness

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

CONTACT:
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DATE PREPARED:
August 29, 2001

NAME OF THE DEVICE:
3i Locator®Abutment System
Classification: DZE
Common Name: Abutment for Endosseous Implant

PREDICATE DEVICES:
Zest Locator® Anchor System

DEVICE DESCRIPTION:
The *3i* Locator Abutment System consists of a titanium alloy socket that is attached to a threaded post for use with titanium endosseous implants having an internal threaded socket. Both devices have a nylon component that has a shape on one end that mates into the titanium socket, while the other end with metal cap is attached to the denture. This arrangement provides snap-fit retention of the denture.The system is identical to the predicate devices, except for a modification to allow use with *3i*'s TG Osseotite implant, and the packaging and sterilization of the system prior to distribution by *3i*.

INTENDED USE:
The *3i* Locator Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

INDICATIONS FOR USE:

- Tissue supported overdentures on 2 to 4 implants
- Partially edentulous overdentures with one or more implants
- Overdentures with a minimum of 3.17mm of interarch distance
- Multiple implants with no greater than 40° of divergence between them

CONTRAINDICATIONS:

- Multiple implants with greater than 40° of divergence between them
- Overdentures with more than 4 implants

PERFORMANCE DATA:

All previously submitted bench testing of the Zest Locator Anchor System has demonstrated satisfactory functional performance in retention and withstanding occlusal forces. The system was also fatigue tested to 5 million cycles, and demonstrated that the fatigue strength of the attachment components is still at least 175 pounds. There are no modifications to the system in the *3i* Locator Abutment System that would demonstrate different results. Sterilized Nylon 101 components (replacement males) were fatigue tested to 18,000 cycles and performed as well as the control group of non-sterilized components.

In conclusion, this 510(k) supports the substantial equivalence of the *3i* Locator Abutment System to its predicate, the Zest Locator Anchor System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Ms. Jacqueline A. Hughes
Director of R/A & Q/A
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K012911
Trade/Device Name: 3I Locater Abutment System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: August 29, 2001
Received: August 30, 2001

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 (section 531-542 of the Act; 21); CFR 1000-1050.

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) 594-4613. 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 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,

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 (if known): K012911

Device Name: *3i* Locator Abutment System

Intended Use

The *3i* Locator Abutment System for endosseous dental implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

Indications for Use

- Tissue supported overdentures on 2 to 4 implants
- Partially edentulous overdentures with one or more implants
- Overdentures with a minimum of 3.17mm of interarch distance
- Multiple implants with no greater than 40° of divergence between them

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012911

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