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K052648

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Jim Banic Regulatory Affairs Specialist Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6932 Fax. 561-514 6316 Email jbanic@3implant.com
Date Prepared	September 20, 2005
Device Name	Patient-Specific Dental Abutments
Classification Name	Dental Abutments
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3630
Predicate Devices	*3i* Patient-Specific Dental Abutments K032263
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.
Device Description	The *3i* Patient-Specific Dental Abutments are designed to match an individual patient. Since each 3i Patient-Specific Dental Abutment is manufactured to match a particular patient according to the doctor's requirements, a specific

K052648

	device description is not possible. However, the *3i* Patient-Specific Dental Abutments are designed in keeping with the general descriptions presented in Section G, unless otherwise specifically requested by the doctor.
Indications for Use	The *3i* Patient-Specific Dental Abutments and Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. It is intend for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.
Technological Characteristics	The *3i* Patient-Specific Dental Abutments contain features and functions which are similar to the currently available *3i* Patient-Specific Dental Abutments [K032263].
Conclusion	The *3i* Patient-Specific Dental Abutments are substantially equivalent to the legally marketed *3i* Patient-Specific Dental Abutments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Mr. Jim Banic
Regulatory Affairs Specialist
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, FLORIDA 33410

Re: K052648
Trade/Device Name: Modification to 3i Patient-Specific Dental Abutments and Overdenture Bars
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: NHA
Dated: September 20, 2005
Received: September 26, 2005

Dear Mr. Banic:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Susan Runner

for Chiu Lin, Ph.D.
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

510(k) Number (if known): K052648

Device Name: 3i Patient Specific Abutments

Indications for Use:

The ***3i*** Patient-Specific Dental Abutments and Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. It is intend for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K052648