K063403

Summary of Safety and Effectiveness

MAR 2 0 2007

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	Tamara Nelson Regulatory Affairs Supervisor Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6923 Fax. 561-514 6316 Email: tnelson@3implant.com
Date Prepared	03 November 2006
Device Name	Conical Angled Abutments
Classification Name	Endosseous Dental Implant Abutment
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3630
Predicate Devices	Conical Abutment -> K933462
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.
Device Description	The Conical Angled Abutments are designed to interface with 3i's internal and external connected implants. They will be available in 17° and 25° angles. The seating surface will be 4.1mm and 5.0mm diameters and the transmucosal tissue heights will be 2.0mm and 4.0mm. They will be manufactured out of Titanium Alloy.
Indications for Use	3i's Conical Angled Abutments are indicated for use in single and multiple unit cases and as custom copings where tissue depth, as measured from the crest of the tissue to the

	shelf of the implant; angulation of the implant in relation to other implants or adjacent dentition; and, interarch distance measured form the shelf of the implant to the opposing dentition, provide for improved emergence profiles and contours for esthetic restorations.
Technological Characteristics	The Conical Angled Abutments contain features and functions similar to the currently available Conical Abutments.
Conclusion	The Conical Angled Abutments in this submission are substantially equivalent to the legally marketed Conical Abutments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tamara Nelson
Regulatory Affairs Supervisor
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

MAR 2 0 2007

Re: K063403
Trade/Device Name: Conical Angled Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 9, 2007
Received: March 12, 2007

Dear Ms. Nelson:

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,

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

510(k) Number (if known): K062403

Device Name: Conical Angled Abutments

Indications for Use:

3i's Conical Angled Abutments are indicated for use in single and multiple unit cases and as custom copings where tissue depth, as measured from the crest of the tissue to the shelf of the implant; angulation of the implant in relation to other implants or adjacent dentition; and, interarch distance measured form the shelf of the implant to the opposing dentition, provide for improved emergence profiles and contours for esthetic restorations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
...of Anesthesiology, General Hospital,
...on Control, Dental Devices
...Number: K062403

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