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5. 510(k) Summary

FEB - 2 2009

This summary of safety and effectiveness information is being provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is:_____

Submitter's Information:

Vitali Bondar, D.D.S.
Owner and CEO
KAT Implants LLC
15 Ryc Street, Suite 115
Portsmouth, NH 03801
Phone: (603) 427-0084
Fax: (603) 427-0045

Date the Summary was Prepared: November 20, 2008

Device name:

- **Common Name:** Dental Implant and Abutment
- **Trade Name:** KAT Implant System
- **Classification name:** Endosseous Dental Implant (21 CFR 872.3640, Product code DZE) and Endosseous Dental Implant Abutment (21 CFR 872.3630, Product Code NHA)

Device classification: Class II

Intended use

KAT Implant System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.

KAT 3.0mm implant is indicated for use in maxillary lateral or mandibular lateral and central incisors in single or multiple units to support prosthesis, such as artificial teeth. The implant can be placed in extraction sites or healed alveolar ridges and can be immediately loaded when good primary stability is achieved and the functional load is appropriate. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.

KAT 2.5mm is a self-tapping titanium alloy threaded screw indicated for transitional and long-term intra-bony applications, such as providing support for transitional or long term crowns, bridges and dentures. KAT 2.5mm may also be used for inter-radicular transitional application.

The legally marketed devices to which the equivalence is claimed [807.92(a)(3)]:

Predicate device: LaminOss® Osteocompressive Dental System
Applicant: Impladent Inc. (USA)
510(k) number: K982925

Predicate device: Bicon Dental Implant 4.5 x 6.5mm
Applicant: Bicon Inc. (USA)
510(k) number: K050712

Predicate device: IMTEC Sedax MDI 1.8mm
Applicant: IMTEC Corporation (USA)
510(k) number: K031106

Predicate device: OsseoSpeed 4.0S-6mm
Applicant: Astra Tech Inc. (USA)
510(k) number: K063779

Predicate device: OsseoSpeed Narrow
Applicant: Astra Tech Inc. (USA)
510(k) number: K080396

KAT Dental Implant System has the following similarities to the predicate devices:

- Has the same intended use;
- Uses the same operating principles;
- Incorporates the same basic design;
- Incorporates the same materials; and
- Is packaged and sterilized using the same or equivalent materials and processes.

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Description of Device

KAT implant system consists of dental implants, implant abutments, healing abutments, temporary abutments, screw retained framework abutment, spacer, cylinder, healing collar and the instruments for placement and restoration of the implants. KAT implants are supplied in 2.5, 3.0, 3.5, 4.3 and 5.0mm diameters. KAT 2.5 and 3.0mm implants are supplied in 10, 12 and 14mm length. KAT 3.5mm is supplied in 8, 10, 12 and 14mm length. KAT 4.3 and 5.0mm implants are supplied in 6, 8, 10, 12 and 14mm length. External V-shaped thread is utilized to screw the implants into the bone. Horizontal fins are placed in between the thread and the abutment receiving portion of 3.5, 4.3 and 5.0mm implants. All implants have 3.1mm diameter 1.5 degree taper abutment receiving post. KAT abutments are available in 4.2, 4.7, 5.5 and 6.5mm diameter. KAT abutments can be attached to any KAT implant via locking taper connection.

Material composition

Titanium alloy Ti-6Al-4V ELI is used to manufacture implants, abutments and other components of the KAT implant system conforming to ASTM F136. Surfaces of the implants and abutments include: machined surfaces and aluminum oxide grit blasted and nitric acid passivated surfaces.

Summary of the technological characteristics:
The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices. The components of KAT dental implant system are substantially equivalent to the listed predicate devices because of the similarities in design, material and intended use.

Conclusions Drawn:

KAT Dental Implant System has the same intended use as, and technological characteristics similar to the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety and effectiveness. Therefore the new implant system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

Vitali Bondar, D.D.S.
Owner and Chief Executive Officer
KAT Implants L.L.C.
15 Rye Street, Suite 115
Portsmouth, New Hampshire 03801

Re: K083544
Trade/Device Name: KAT Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 27, 2009
Received: January 27, 2009

Dear Dr. Bondar:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use Statement

510(k) Number: K083544

Device Name: KAT Implant System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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