K073461

510(k) Summary:

Ortho Anchor Screws

JAN 25 2008

Company Name -
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Establishment Registration Number: 3004203816

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Date prepared: November 9, 2007

Trade Name: Ortho Anchor Screws

Classification name: Implants, Endosseous, Orthodontic

Common/usual name: Ortho Anchor Screws

Product Code: OAT

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Predicate Device:
Dual Top Anchor System Screws from Jeil Medical Cooperation, P.O. Box 7007, Deerfiled, IL 60015, cleared under 510(k) no. **K033767**

Description of the device:
The MIS Ortho Anchor Screws are self-tapping screws that are used as fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth.

The screw is manufactured as one piece screw made of medical grade 5 Titanium alloy complying with the standard ASTM F136-02. The upper head of the screw has a cross-hole through which a wire can pass to fix the mandible and maxilla in the orthodontic procedure. The screw head is special designed to assist the use of orthodontic appliances.

The Ortho Anchor Screws are provided in several lengths ranging between 5-10mm and diameters of 1.4mm, 1.6mm and 2mm. The screws are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are supplied sterile.

Indications for Use:
The Ortho Anchor Screws are intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are intended for single use only.

Substantial Equivalence:
The MIS Ortho Anchor Screws have the same intended use as the **Dual Top Anchor System Screws** from Jeil Medical Cooperation, P.O. Box 7007, Deerfiled, IL 60015, cleared under 510(k) no. **K033767**, and have equivalent performance characteristics. Both products are manufactured from the same Titanium alloy. All other technological characteristics are similar and show equivalent performance capabilities. The Ortho Anchor Screws are therefore substantially equivalent to the predicate devices.

Conclusion -
The evaluation of the Ortho Anchor Screws does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Ms. Iman Khorshid
Quality Manager
M.I.S. – Implants Technologies Limited
P.O.B. 110
Shlomi Industrial Zone
Shlomi,
ISRAEL 22832

Re: K073461
Trade/Device Name: Ortho Anchor Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: November 9, 2007
Received: December 10, 2007

Dear Ms. Iman Khorshid:

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

INDICATIONS FOR USE

510(k) Number (if known): K073461

Device Name: Ortho Anchor Screws

Indications for Use: The Ortho Anchor Screws are intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are intended for single use only.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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