JUN - 9 2004

K040807

MIS

510(k) Summary

10. **Company Name –**

MIS – Implant Technologies Ltd.
POB 110 Shlomi Industrial Zone
Shlomi 22832
ISRAEL

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QA Manager
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US Agent: Motti Weisman – VP Marketing
MIS Implants Technologies Inc.
278 Broadway
Elmwood Park, NJ 07407
Phone: (201) 797-9144
Fax: (201) 797-9145
E-mail: mis.service@verizon.net

Date prepared: March 15, 2004

2. **Device Name –**

Proprietary name: MIS Dental Implant System
Common / Usual Name: Endosseous Dental Implant
Trade Name: MIS Dental Implant System

The device has been classified in Class III under the following classification:

Classification name	Product Code	Regulation No.	Panel Identification
Endosseous implant	DZE	872.3640	DentalDevices Panel

3. **Predicate Devices –**

- **3i Dental Implant System** from Implant Innovations Ltd, Palm Beach Gardens, FL, cleared under 510(k) no. **K022009** (for two stage implants)

- **3i Dental Implant Accessories** from Implant Innovations Ltd, Palm Beach Gardens, FL, cleared under 510(k) no. **K022113** (for accessories)

- **ITI Dental Implant System** from Straumann USA, Waltham, MA, cleared under 510(k) no. **K030007** (for one stage implants)

4. **Description of the Device –**
The MIS Dental Implant System consists of one and two stage implants, internal and external hexagonal; cover screw and healing caps; abutment systems and suprastructures; surgical instruments.
Hereby is a description of each of the components:

Implants:
One- or two-stage dental implant devices, both internal hexagonal and external hexagonal, including self-tapping implants of different dimensions. All implants are manufactured from medical grade 4 (GD-4) pure titanium, which meets requirements of standard ASTM F67-95.

Cover screw and healing caps:
The implants are supplied together with cover screws and healing caps, manufactured from titanium grade 4. The cover screws and healing cups are placed in the implant during the integration period between the implant and the bone. They completely occlude the internal surface, keeping it free from ingrowth of bone and debris. The parts are supplied sterile together with the implant in the same individual package.

Abutment systems and suprastructures:
Anatomic abutments are used in conjunction with the two-stage implants for screw retained reconstruction. The selection of the abutments is made at the beginning of the prosthetic procedure and is based on measurement of the gingival thickness. The abutments fit in/on the hexagonal part of the implant and deliver maximum stability with the use of the screw.

Direct systems for screw retained construction and for cemented reconstruction are included in the system.

Cerasthetic abutments manufactured from ceramic and titanium, as well as gold-plastic cylinder abutments manufactured from burn-out plastic and gold are also available in the submitted system.

Additional suprastructures include ball attachment system and bar and screw attachment system. Those systems are manufactured from titanium, gold, stainless steel or burn-out plastic.

Surgical instruments:
The range of instruments made available as part of the MIS Dental Implant System includes drills, adapters, ratchet wrench and depth and direction indicators. The instruments are manufactured from titanium or stainless steel and supplied in kits specially designed kit packages.

5. **Indications for Use –**
The MIS Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

6. **Substantial Equivalence –**
The MIS Dental Implant System has the same intended use as the 3i Dental Implants and 3i Dental Implant Accessories from Implant Innovations Ltd, Palm Beach Gardens, FL, cleared under 510(k) no. K022009 and K022113 and ITI Dental Implant System cleared under 510(k) no. K030007 and has equivalent performance characteristics. Those product systems contain implants, cover screws and healing cups, abutments and the applicable surgical instruments. All other technological characteristics are similar and both devices show equivalent performance capabilities.

7. **Conclusion -**
The evaluation of the MIS Dental Implant System 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

JUN - 9 2004

MIS-Implant Technologies Limited
C/O Mr. Motti Weisman
Vice President Marketing
MIS Implants Technologies, Incorporated
278 Broadway
Elmwood Park, New Jersey 07407

Re: K040807
Trade/Device Name: MIS Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE, NHA
Dated: April 22, 2004
Received: April 27, 2004

Dear Mr. Weisman:

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.

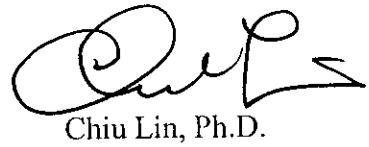
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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): K040807

Device Name: MIS Dental Implant System

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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

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