K080458

DEC 17 2008

510(k) Summary:

MIS Crest Widener

Company Name -
MIS - Implants Technologies Ltd.
POB 110 Shlomi Industrial Zone
Shlomi 22832
ISRAEL
Telephone: +972-4-980-9966
Fax: +972-4-980-9944

Establishment Registration Number: 3004203816

Contact Name: Iman Khorshid
Quality Manager
Telephone: +972-4-980-9966
Fax: +972-4-980-9944
E-mail: iman@mis-implants.com

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: motti@misimplants.com

Date prepared: February 10, 2008

Trade Name: MIS Crest Widener

Classification name: External mandibular fixator and/or distractor

Common/usual name: MIS Crest Widener

Product Code: MQN

Regulation No.: 872.4760

Class: II

Panel identification: Dental Devices Panel

Predicate Device:

1. Alveolar Ridge Distractor from SYNTHES (USA). P.O.Box 1766, 1690 russell road , paoli, PA 19301 1222 cleared under 510(k) no. **K043555.**
2. TRACK 1.0 & 1.5 MM SYSTEMS-TISSUE REGENERATION BY CALLUS DISTRACTION from KLS-Martin, L.P. 3234 ella ln., new port richey, FL 34655, cleared under 510(k) no. **K002152**
3. ORAL OSTEODISTRACTION ROD APPLIANCE (ROD 5) from ORAL OSTEODISTRACTION L.P. , 962 allegro ln. apollo beach, FL 33572, cleared under 510(k) no. **K042278.**

Description of the device:

The MIS crest widener is used to widen a narrow alveolar crest which has sufficient height so as to prepare the ridge for implantation. With this technique, bone augmentation is avoided and the implant is placed in the correct lateral position .
The Crest widener is made of medical grade 5 Titanium alloy complying with the standard ASTM F136-02.
The device consists of 4 arms, 2 on each side, connected with guiding pins and an activating screw. The Crest Widener is inserted after cutting 3 mucoperiosteal incisions (without stripping the bone) cutting and splitting the narrow alveolar crest. By rotating the activating screw, each pair of arms moves apart from the other 2 arms, thus pushing the buccal cortical bone apart. The device is supplied with a fine Titanium ligature for attachment to a neighbor tooth during the treatment period.

Activating starts 5 - 7 days (latency period) after the insertion of the device. By separating the cortical plates, new bone is created in between (Distraction Osteogenesis)..

The device is not provided sterile and should be sterilized before use.

Indications for Use:

The MIS Crest Widener is intended to:
- Preparing the narrow alveolar crest for implantation as an alternative to bone augmentation.
The device is used temporary and is removed after the treatment has been completed.

Substantial Equivalence:

The MIS Crest Widener has the same intended use as its predicate devices:
1. Alveolar Ridge Distractor from SYNTHES (USA). P.O.Box 1766, 1690 russell road , paoli, PA 19301 1222 cleared under 510(k) no. **K043555.**
2. TRACK 1.0 & 1.5 MM SYSTEMS-TISSUE REGENERATION BY CALLUS DISTRACTION from KLS-Martin, L.P. 3234 ella ln., new port richey, FL 34655, cleared under 510(k) no. **K002152**
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The MIS Crest Widener show equivalent performance capabilities comparing to its predicate devices. The predicate devices are made either of Titanium or stainless steel and used to distract the mandible and / or the maxilla. The devices have the same distraction concept. The use of a screwdriver for activation is similar for all the devices. The devices remain in the body similar period of time until they are removed.
The MIS Crest Widener is therefore substantially equivalent to the predicate devices.

Conclusion -
The evaluation of the MIS Crest Widener does not raise any additional concerns regarding safety and effectiveness 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

DEC 17 2008

Ms. Iman Khorshid
Regulatory Affairs and Quality Assurance Manager
MIS – Implants Technologies Limited
P. O. Box 110, Shlomi Industrial Zone
Shlomi
ISRAEL 22832

Re: K080458
Trade/Device Name: MIS Crest Widener
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 7, 2008
Received: December 9, 2008

Dear Ms. 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.

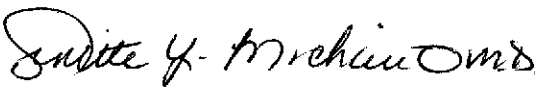
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080458

INDICATIONS FOR USE

510(k) Number (if known): K080458

Device Name: MIS Crest Widener

Indications for Use: The MIS Crest Widener is intended to:

- Preparing the narrow alveolar crest for implantation as an alternative to bone augmentation.

The device is used temporary and is removed after the treatment has been completed. The device is 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)

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

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