K110756

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MIS Implants Technologies Ltd.

APR 28 2011

510(k) Summary:

PerioPatch

Company Name: MIS Implants Technologies Ltd.
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Establishment Registration Number: 3004203816

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E-mail: service@misimplants.com

Date prepared: February 13, 2011

Trade Name: PerioPatch

Classification name: Hydrogel wound dressing

Common/usual name: Dressing wound

Product Code: MGQ, FRO

Regulation No.: 878.4022

Class: Unclassified

Panel identification: General & Plastic Surgery

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Predicate Device:

PerioPatch from Izun Pharmaceuticals Corporation, Rockefeller Plaza Center, 7th Floor, 1230 Avenue of the Americas, Manhattan, New York, 10020, USA, cleared under 510(k) K103054.

Description of the device:

PerioPatch is a hydrogel wound dressing for use in the oral cavity. It is a hydrogel with an occlusive ethyl cellulose backing to support and help the hydrogel conform to the wound, thereby providing protection and coverage to the wound.

The dressing is made entirely of GRAS natural ingredients, commonly used in ingested products, which absorb moisture and become a hydrogel. These materials adhere to the wound for up to 5-6 hours.

The patch is self-adhesive after contact with moist tissue and provides an absorptive and flexible barrier over the affected area and as such protects the inflamed areas and lesions in the mouth from contact with the rest of the oral environment, thereby preventing irritation and painful aggravation of the affected area.

Indications for Use:

PerioPatch is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chaffing and traumatic ulcers, abrasions caused by braces and ill fitting dentures, and lesions associated with oral surgery.

PerioPatch operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.

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Substantial Equivalence:

PerioPatch is equivalent to its predicate device based on a comparison of the intended use, product technical characteristics and performance. Both products become self-adhesive hydrogels upon contact with moisture, exhibiting the same hydrophilic product characteristics.

Conclusion:

The evaluation of PerioPatch does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Iman Khorshid
Vice President Quality Assurance & Regulatory Affairs
Mis Implants Technologies, Limited
Bar Lev Industrial Park
P.O. Box 7
Bar Lev Industrial Park
Israel 20156

APR 2 8 2011

Re: K110750
Trade/Device Name: PerioPatch
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MGQ
Dated: February 13, 2011
Received: March 17, 2011

Dear Mr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110750

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mis Implants Technologies Ltd.

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: PerioPatch

Indications for Use: PerioPatch is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chaffing and traumatic ulcers, abrasions caused by braces and ill fitting dentures, and lesions associated with oral surgery. PerioPatch operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.

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

510(k) Number: K110750