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K062436

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: July 24, 2006

Submitter:

Name:	Mondeal Medical Systems GmbH
Address:	Moltkestr. 39 78532 Tuttlingen Germany
Contact Person:	Ralph Duerr
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Product:

Trade Name:	SIS Sinus Implant Stabilizer
Classification:	Class II
Common Name:	Bone Plate
Classification Name:	Endosseous Implant

Predicate Devices:

- Synocta Prosthetics, K990342
- Mini Bone Plate System, K951392
- Micro Titanium Plate System, K951688
- Lin/Liou Orthodontic Mini Anchor System (LOMAS), K042345 & K050257

Device Description: The SIS Sinus Implant Stabilizer consists of a titanium plate provided with 3 large perforations for screw fixation of implants for premolars and first molars. It may be additionally secured in place with titanium microscrews and is provided in two sizes for use with different implant systems.

Intended Use: The SIS Sinus Implant Stabilizer is intended to provide a fixed anchorage point to stabilize dental implants in the sinus region, enabling sinus augmentation and implantation to be carried out in one session.

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Performance Data: Testing was performed to support substantial equivalence to the predicate devices. The SIS Sinus Implant Stabilizer met all specified design and performance requirements.

K062436 2/2

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Sterilization The SIS Sinus Implant Stabilizer is intended for single use and may be offered either sterile by gamma radiation or non-sterile for autoclave steam sterilization.

Conclusion: Based upon the product technical information provided, intended use and performance information provided in this premarket notification, as well as similarity to legally marketed devices, Mondeal Medical Systems GmbH considers the **SIS Sinus Implant Stabilizer** to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mondeal Medical Systems GmbH
C/O Ms. Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Amstel 320-I
1017 AP Amsterdam
THE NETHERLANDS

JUL 3 0 2007

Re: K062436
Trade/Device Name: SIS Sinus Implant Stabilizer
Regulation Number: 21 CFR 872.4760
Regulation Name: Endosseous Dental Implant Accessories
Regulatory Class: II
Product Code: JEY
Dated: July 4, 2007
Received: July 13, 2007

Dear Ms. Scherp:

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.

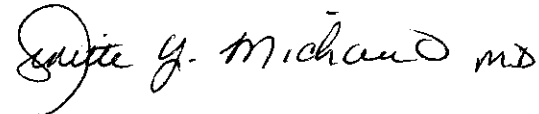
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K062436

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: SIS Sinus Implant Stabilizer

Indications for Use: The SIS Sinus Implant Stabilizer is intended to provide a fixed anchorage point to stabilize dental implants in the sinus region, enabling sinus augmentation and implantation to be carried out in one session.

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

510(k) Number: K062436