4. Summary of Safety and Effectiveness Information

K050924

MAY 27 2005

Submitted by:	**Merete Medical GmbH** **Alt Lankwitz 102, 12247 Berlin** **Germany**
FDA Registration Number:	**3002949614**
Contact Person:	**Jenik Radon,** **269 West Seventy-First Street** **New York, N.Y. 10023** **Tel. 212- 496-2700 Fax 212- 724-3393**
Trade/Device Name:	**Merete DuoThread™ Bone Screw**
Device Classification:	**21 CFR 888.3040** **Smooth or threaded Metallic bone fixation fastener**
Proposed Regulatory Class:	**Class II**
Product Code:	**HWC**
Predicate Devices:	**Landos Scarf Thread-Head™ Head Screw(K971070)** **Zimmer Herbert Bone Screw (K792022)**
Description of Device:	**The DuoThread™ Bone screw is a fully or partially threaded cannulated bone fixation screw with a threaded head. The screw is made of titanium alloy (Ti-6Al-4V) ASTM F-136 in 3 mm diameter and in lengths 10 mm to 34 mm (in 2 mm increments).**
Intended use:	**Small bone fracture fixation. Fixation and stabilization of bones of the feet in case of an osteotomy or fusion such as Scarf-Osteotomy, Chevron-Austin osteotomy, Akin-osteotomy, Closing wedge osteotomy, MPG-Athrodesis as well as for the fixation of almost all common osteotomies of the first metatarsal.**
Technological Characteristics:	**The DuoThread™ bone screws are similar to legally marketed predicate devices listed above in that they share similar indications for use, are manufactured from similar materials and incorporate similar technological characteristics.**
Potential Risks:	**The risks associated with this device are the same as with any metallic internal fixation device. These include but not limited to the following: Delayed or nonunion which may lead to breakage of the implant. Bending or fracture of the implant. Metal sensitivity, or allergic reaction to a foreign body. Pain, discomfort, or abnormal sensation due to the presence of the device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Merete Medical GmbH
C/o Mr. Jenik Radon
269 West Seventy-First Street
New York, New York 10023

Re: K050924
Trade/Device Name: DuoThread™ Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 13, 2005
Received: April 13, 2005

Dear Mr. Radon:

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) 276-0120. 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,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use DuoThread™ Bone Screw

Indications for Use
DuoThread™ Bone Screw

510 (k) Number : K050924

Device Name: DuoThread™ Bone Screw

Indications For Use:

Small bone fracture fixation. Fixation and stabilization of bones of the feet in case of a osteotomy or fusion, such as Scarf-Osteotomy, Chevron-Austin Osteotomy, Akin-Osteotomy, Closing wedge osteotomy, MPG-Arthrodesis as well as for the fixation of almost all common osteotomies of the first metatarsal.

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 IN NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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