3 Summary of Safety and Effectiveness

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JUL 18 2008

Submitted by: Merete Medical GmbH
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FDA Registration Number: 3002949614

Contact Person: Jörg Mietzner
Merete Medical, Inc.
49 Purchase Street
Rye, New York 10580
Phone: 914 967 1532

Device Name: Merete 3.0 mm and 3.5 mm Locking Screws

Device Classification: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.

Product Code: HWC

Proposed Regulatory Class: Class II

Predicate Device:

- Synthes Small Fragment Locking Compression Plate (LCP) - K000684
- Smith & Nephew Locking Bone Plate System - K033669
- DARCO Locking Bone Plate System – K061808
- Merete MetaFix Small Fragment Locking Bone Plate System - K050457
- Merete BLP Small Fragment locking Bone Plate System – K063487

Device Description:
The screws are fully threaded and self-tapping with a threaded head to lock into Merete Locking plates. Locking screws/plates incorporate a screw-to-plate locking feature which creates a locked, fixed angle construction to hold fracture or osteotomy reduction. The screws are made of titanium (ASTM F-136) and are available in the lengths from 12 mm to 32 mm in 2 mm increments.

Intended use:
The Merete 3.0 mm and 3.5 mm Locking Screws are intended to be used in combination with Merete Locking plates for adult and pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulner, fibula, metacarpals, metatarsals, Hallux Valgus osteotomy corrections, middle hand and middle foot bones, particular in osteopenic bone.

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Technological Characteristics:

The Merete 3.0 mm and 3.5 mm Locking Screws are similar to the screws of the 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 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

Merete Medical, Inc.
% Mr. Jörg Mietzner
49 Purchase Street
Rye, NY 10580

JUL 18 2008

Re: K081513
Trade/Device Name: Merete 3.0 mm and 3.5 mm Locking Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 30, 2008
Received: May 30, 2008

Dear Mr. Mietzner:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Indications for Use

Indications for Use

510(k) Number (if known): K081513

Device Name: Merete 3.0 mm and 3.5 mm Locking Screws

Indications for Use:

The Merete 3.0 mm and 3.5 mm Locking Screws are intended to be used in combination with Merete Locking plates for adult and pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulner, fibula, metacarpals, metatarsals, Hallux Valgus osteotomy corrections, middle hand and middle foot bones, particular in osteopenic bone.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K081513