1 510(k) Summary

Submitted by:	Merete Medical GmbH Alt Lankwitz 102, 12247 Berlin, Germany
FDA Registration Number:	3002949614
Contact Person:	SEP - 2 2009 Jörg Mietzner Merete Medical, Inc. 49 Purchase Street Rye, New York 10580 Phone: 914 967 1532
Device Name:	Merete Compression Screws
Device Classification:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Product Code:	HWC
Proposed Regulatory Class:	Class II

Device Description:
Merete Compression Screws are cannulated, self-drilling/self-tapping, dual pitched screws with a threaded head which can be countersunk into the bone. The screws are provided in the diameters 3.0 mm, 4.3 mm and 6.5 mm in various lengths and are available in Titanium alloy (Ti-6Al-4V).

Intended use:
Merete Compression Screws are indicated for fracture fixation and reconstruction of various bones, including

- osteotomies in the foot (as Hallux Valgus treatment) or hand,
- arthrodesis in hand, foot or ankle surgery,
- fixation of bone fragments in long bones or small bone fractures.

The size of the chosen screw should be adapted to the specific indication.

Predicate Device:
Screws 3.0 mm and 4.3 mm:
K050346 NewDeal Stabilization Screw

Screw 6.5 mm:
K991151 Vilex/Duval/Orthex Cannulated Bone Screw

Substancial Equivalence:
Merete Compression Screws are similar to legally marketed predicate device listed above in that they share similar indications for use, are manufactured from similar materials and incorporate similar technological characteristics.

2 Bending Strength Rationale

The referenced predicate devices in K050346 and K991151 are similar in their dimensions to the Merete Compression Screws 3.0, 4.3 and 6.5 mm as they present a similar core diameter, thread diameter as well as a similar cannulation.

As the predicate devices are manufactured from similar materials (Ti-6Al-4V) too, the bending strength of the Merete Compression Screws 3.0, 4.3 and 6.5 mm can be supposed as similar as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

SEP - 2 2009

Re: K091798
Trade/Device Name: Merete Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 20, 2009
Received: August 24, 2009

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 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.

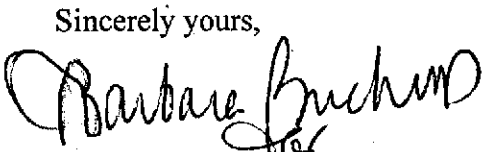
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

1 Indications for Use Statement

Indications for Use

510(k) Number (if known): K091798

Device Name: Merete Compression Screws

Indications for Use:
Merete Compression Screws are indicated for fracture fixation and reconstruction of various bones, including

- osteotomies in the foot (as Hallux Valgus treatment) or hand,
- arthrodesis in hand, foot or ankle surgery,
- fixation of bone fragments in long bones or small bone fractures.

The size of the chosen screw should be adapted to the specific indication.

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) for MXM
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091798