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2. 510(k) Summary

Submitted by:
Merete Medical GmbH
Alt Lankwitz 102,
12247 Berlin, Germany

APR 22 2009

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 Locking Bone Plate System

Device Classification: 21 CFR 888.3030 Single/multiple component Metallic bone fixation appliances and accessories

Product Code: KTT

Proposed Regulatory Class: Class II

Predicate Device:
- DARCO Locking Plate System – K067808
- Merete BLP™ Small Fragment Locking Bone Plate System – K063487
- Merete 3.0 mm and 3.5 mm Locking Screws – K081513

Device Description:
The Merete Locking Bone Plate System consists of contoured, anatomically shaped locking bone plates in various sizes and different curvatures, Merete 3.0mm and 3.5mm locking screws and cannulated 3.0mm compression screws. The system is made of titanium alloy Ti-6Al-4V.

Intended use:
The Merete Locking Bone Plate System can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

Technological Characteristics:
The components of the Merete Locking Bone Plate System 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 22 2009

Re: K090063
Trade/Device Name: Merete Locking Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: January 9, 2009
Received: January 23, 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.

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its 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

1. Indications for Use Statement

Indications for Use

510(k) Number (if known): K090063

Device Name: Merete Locking Bone Plate System

Indications for Use:
The Merete Locking Bone Plate System can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

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

510(k) Number K090063

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)