2. 510(k) SUMMARY

DEC 20 2010

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

FDA Registration Number:
3002949614

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

Proprietary Name:
TwistCut™ EndoSorb™ Screws

Device Classification:
Smooth or threaded metallic bone fixation Fastener (888.3040)

Product Code:
JDW

Subsequent Product Code:
HWC

Proposed Regulatory Class:
Class II

Legally Marketed Devices To Which Substantial Equivalence is Claimed:
ProToe™ EndoSorb™ Small Hammer Toe Pin, Merete (K100414)
Reunite Screws, Biomet (K992301)

Intended Use:
The TwistCut™ EndoSorb™ Bone Screws are indicated for use in the presence of appropriate immobilization in the following procedures:

1. for metacarpal and phalangeal fusion and fracture
2. or repair of hallux valgus deformity (bunion).

Device Description:
The TwistCut™ EndoSorb™ Bone Screws are made out of the absorbable EndoSorb™ material. EndoSorb™ is a polyester derivative of L-Lactic and glycolic acids.
Poly(L-lactide-co-glycolide) material (PLGA) degrades and absorbs in vivo by hydrolysis into L-lactic and glycolic acids, which are then metabolized by the body. The screw head provides a hexagonal twist off portion to enable screw head to be flush with the bone.

Substantial Equivalence:

The TwistCut™ EndoSorb™ Bone Screws similar to legally marketed predicate device listed above in that it shares similar indications for use, is manufactured from similar materials and incorporate similar technological characteristics. Any differences have been found to have no obvious effect on the performance, function, or intended use of the prosthesis.

The following bench tests were performed:

- *In vitro* degradation test (determination of decreasing strength and inherent viscosity)
- Determination of inherent viscosity, glass transition temperature and crystallinity
- Brakeage strength and insertions torque
- Long-term stability of package and subject device
- Stability test under extreme transport conditions
- Temperature limit for storage
- A geometrical and a material comparison of the subject and the predicate devices were provided. This information served as a basis for a determination of substantial equivalence.

The predicates for the subject device are ProToe™ EndoSorb™ Small Hammer Toe Pin, Merete (K100414); Reunite Screws, Biomet (K992301).

Software Documentation:

No software is needed for the use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Merete Medical GmbH
% Mr. Emmanuel Anapliotis
President & CEO
Alt Lankwitz 102
12247 Berlin, Germany

DEC 20 2010

Re: K102777
Trade/Device Name: TwistCut EndoSorb Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: JDW, HWC
Dated: September 21, 2010
Received: September 24, 2010

Dear Mr. Anapliotis:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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): K102777

Device Name: TwistCut™ EndoSorb™ Bone Screw

Indications for Use:

The TwistCut™ EndoSorb™ Bone Screws are indicated for use in the presence of appropriate immobilization in the following procedures:

1. for metacarpal and phalangeal fusion and fracture
2. or repair of hallux valgus deformity (bunion).

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) for M. Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices