3 Summary of Safety and Effectiveness

MAY – 8 2008

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

FDA Registration Number: 3002949614

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

Device Name: Merete ToeMobile™ Anatomical Great Toe Resurfacing System

Device Classification: Prosthesis, Toe (metatarsophalangeal), Joint, Metal/polymer, Semi-constrained

Product Code: LZJ

Proposed Regulatory Class: unclassified (reason: Pre-Amendment)

Predicate Device:
- Biomet Total Toe System, K920446
- Kinetikos Medical Kinetik Great Toe System, K924724

Device Description:
The Merete ToeMobile™ Anatomical Great Toe Resurfacing System is a two-piece prosthesis that replaces the metatarso-phalangeal joint by complete functional preservation of the joint and maintaining of the sesamoid complex.
The prosthesis consists of an anatomically shaped and polished metatarsal implant, made of CoCrMo, which glides on a polyethylene inlay that is preassembled on a conically shaped phalangeal component made of titanium alloy Ti-6Al-4V.
Metatarsal and Phalangeal implant are intended for cemented use only.

Following implant sizes are available:

- Metatarsal Implant
→ Size -1, 0, 1, 2

- Phalangeal Implant (Titanium component with PE-Inlay in three different heights)
→ Size 0.1, 0.2, 0.3 ; 1.1, 1.2, 1.3 ; 2.1, 2.2, 2.3

Materials:
The Materials used for the ToeMobile™ Anatomical Great Toe Resurfacing System are approved biocompatible materials and substantially equivalent to competitive devices previously cleared for market:

Metatarsal Implant:
- Cobalt chromium alloy CoCrMo according to ASTM F-75 and ISO 5832-4

Phalangeal Implant (Phalangeal Titanium Component with PE-Inlay):
- Titanium alloy Ti-6Al-4V according to ASTM F-136 and ISO 5832-3
- UHMWPE according to ASTM F-648 and ISO 5834-2

Intended Use:
The Merete ToeMobile™ Anatomical Great Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint. The device is intended for cemented use only. Indications for use include:
- Painful degenerative metatarso-phalangeal joint change
- Hallux rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions- after moderate proximal phalanx resection

Substantial Equivalence:
The components of the Merete ToeMobile™ Anatomical Great Toe Resurfacing System 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. Any differences have been found to have no obvious effect on the performance, function, or intended use of the prosthesis.

Potential Risks:
Potential risks associated with this device are the same as with any joint replacement device. These include but not limited to the following:
- Metal sensitivity, or allergic reaction to a foreign body
- Pain, discomfort, or abnormal sensation due to the presence of the device
- Infection or painful, swollen or inflamed implant side
- Loosening or dislocation of the prosthesis
- Fracture of the implant
- Bone resorption or over-production

Software Documentation:
No software is needed for the use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Merete Medical GmbH
% Merete Medical, Inc.
Ms. Donna Coleman
49 Purchase Street
Rye, NY 10580

MAY - 8 2008

Re: K072251
Trade/Device Name: Merete ToeMobile™ Anatomical Great Toe Resurfacing System
Regulation Number: Unclassified
Regulation Name: Prosthesis, Toe (metatarsophalangeal), Joint, Metal/polymer, Semi-constrained
Regulatory Class: Unclassified
Product Code: LZJ
Dated: April 25, 2008
Received: April 28, 2008

Dear Ms. Coleman:

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

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): K072251

Device Name: Merete ToeMobile™ Anatomical Great Toe Resurfacing System

Indications for Use:
The Merete ToeMobile™ Anatomical Great Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint. The device is intended for cemented use only. Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallux rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions- after moderate proximal phalanx resection

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)

Neil A. Ogden for mxm

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K072251