



Food and Drug Administration
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Merete Medical GmbH
% Mr. Matthias Möllmann
Senior Vice President
Merete Technologies Incorporated
One Lincoln Center
18W140 Butterfield Road
Oakbrook Terrace, Illinois 60181

April 29, 2016

Re: K160548

Trade/Device Name: MC-Subtalar™ II

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: HWC

Dated: February 23, 2016

Received: February 29, 2016

Dear Mr. Möllmann:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known)
K160548

Device Name
MC-Subtalar™ II

Indications for Use (Describe)

The MC-Subtalar™ II screw system is for the correction of flexible flat feet in children (6 to < 12 years of age) and adolescence (12 to < 13 years of age). It is intended to block medial and plantar pronation of the talus, while, allowing normal subtalar joint motion.

Specific indications for use include:

- Flexible flat feet in children and adolescence,
- Progression medial talus protrusion,
- Loss of longitudinal arch,
- Pain along the tibialis posterior,
- Age > 6 years, after conservative treatment did not result in a flat foot correction,
- Age < 13 years, while the deformity may be corrected manually.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary of Safety and Effectiveness
Information as required by 21 CFR 807.92**

Date Prepared: 25th April 2016

Submitted by: Merete Medical GmbH
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Phone: 630-613-7181

Device Name: **MC-Subtalar™ II**

Common Name: Subtalar Arthroereisis Implant

Classification Names: Smooth or threaded metallic bone fixation fastener – 888.3040

Device Product Code: HWC

Proposed Regulatory Class: Class II

Legally marketed Devices to which substantial Equivalence is claimed:

K133035 Pellegrin Calcaneus Stop Screw, Normed Medizin-Technik GmbH

Reference devices:

K111834 Disco Subtalar Implant, Trilliant Surgical LTD

K152187 Foot surgery screws, Merete Medical GmbH

Device Description:

The MC-Subtalar™ II screws are partly threaded, cannulated and self-tapping screws. They are designed to be implanted into the calcaneus bone of the foot for subtalar extra-articular arthroereisis. A hexagonal shaped shaft end allows easy adjustment while operation. The screws are made of X2CrNiMo 18-15-3 stainless steel and are also available made of Ti6Al4V titanium alloy. The MC-Subtalar™ II is offered in sizes of 25 mm, 30 mm and 35 mm and with different head diameter of 6 mm, 8 mm and 10 mm to meet the specific anatomical requirements for various age groups.

Indications for use

The MC-Subtalar™ II screw system is for the correction of flexible flat feet in children (6 to < 12 years of age) and adolescence (12 to < 13 years of age). It is intended to block medial and plantar pronation of the talus, while, allowing normal subtalar joint motion.

Specific indications for use include:

- Flexible flat feet in children and adolescence,
- Progression medial talus protrusion,
- Loss of longitudinal arch,
- Pain along the tibialis posterior,
- Age > 6 years, after conservative treatment did not result in a flat foot correction,
- Age < 13 years, while the deformity may be corrected manually.

Comparison of technological characteristics with the predicate devices:

In order to demonstrate that the MC-Subtalar™ II has the mechanical properties necessary to perform as well or better than the predicate devices, Merete has conducted mechanical analysis and functional worst case tests. These tests have been performed in accordance with ASTM F543-13. Additionally a biomechanical test has been performed to evaluate the durability of the MC-Subtalar™ II screws with 10^6 load cycles in a worst-case scenario. The MC-Subtalar™ II screws have successfully passed the tests and have hereby been proven to be mechanically as good as or better than the predicate devices. Differences in sterilization method and material have been addressed by pointing out to reference devices using the same methods/ materials.

Clinical Data were not needed for these devices to show substantial equivalence.

Substantial Equivalence:

The MC-Subtalar™ II have passed all defined criteria, have performed as well or better than the predicate device and are therefore considered substantially equivalent to the cleared predicate device.