



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

Merete Medical Incorporated
Matthias Möllmann
Official Correspondent
4 Crotty Lane-Suite 118
New York International Plaza
New Windsor, New York 12553

February 12, 2016

Re: K152187

Trade/Device Name: MetaFix™ LS Locking Screws, Merete® Cannulated PCS, Merete® CS Cortical Screws, Merete® Cannulated HCS, DuoThread™ Scarf Screws, TwistCut™ Snap-Off Screws

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: HWC, HRS

Dated: January 8, 2016

Received: January 11, 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 Parts 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" (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 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)

K152187

Device Name

MetaFix™ LS Locking Screws, Merete® Cannulated PCS, Merete® CS Cortical Screws,
Merete® Cannulated HCS, DuoThread™ Scarf Screws, TwistCut™ Snap-Off Screws

Indications for Use (Describe)

Indications for use include fixation of fractures. For specific screw indications please see below.

MetaFix™ LS Locking Screws

- For adult and pediatric patients
- In combination with Merete Locking Plates
- Fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulna, fibula, metacarpals, metatarsals
- Hallux Valgus osteotomy correction, middle hand and middle foot bones and particular in osteopenic bone

Merete® Cannulated PCS

- For adult and pediatric patients
- Fixation of fresh fractures
- Revision procedures
- Joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes

Merete® CS Cortical Screws

- For adult and pediatric patients
- Fixation of fresh fractures
- Revision procedures
- Joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes

Merete® Cannulated HCS

- Fixation of fractures and reconstruction of various bones
- Osteotomies in the foot (as Hallux Valgus) or hand
- Athrodesis in hand, foot or ankle surgery
- Fixation of bone fragments in long bones or small bone fractures

DuoThread™ Scarf Screws

- Small bone fracture fixation
- Fixation and stabilization of bones of the feet
- Osteotomies (Scarf-Osteotomy, Chevron-Austin Osteotomy, Akin-Osteotomy, Closing Wedge Osteotomy)
- Fusion (MPG-Athrodesis)
- Fixation of almost all common osteotomies of the first metatarsal

TwistCut™ Snap-Off Screws

- Fixation of fractures and reconstruction of bones
- Fixation of small bone fragments
- Mono cortical fixation
- Osteotomies (Weil-Osteotomy)
- Fracture fixation in the foot and hand

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”



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

Date Prepared: 06th January 2016

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

Contact Person: Mathias Möllmann
Merete Medical, Inc.
4 Crotty Lane – Suite 118
New York International Plaza
New Windsor, NY 12553
Phone: 914 967 1532

Device Name: **MetaFix™ LS Locking Screws, Merete® Cannulated PCS, Merete® CS Cortical Screws, Merete® Cannulated HCS, DuoThread™ Scarf Screws, TwistCut™ Snap-Off Screws**

Common Name: SCREW, FIXATION, BONE

Classification Names: Smooth or threaded metallic bone fastener - 21 CFR 888.3040
Single/multiple component metallic bone fixation appliances and accessories – 21 CFR 888.3030

Device Product Code: HWC, HRS

Proposed Regulatory Class: Class II

Legally marketed Devices to which substantial Equivalence is claimed:

K081513	Merete 3.0 and 3.5 mm Locking Screws
K120787	Merete Locking Bone Plate System III
K140069	Locking Bone Plate Style 14, MetaFix Locking Screw 3.8, Merete Cannulated PCS 3.0
K130400	Meretec CS, Cortical Screws
K091798	Merete Compression Screws
K050924	Merete DuoThread™ Bone Screw
K051323	Merete Twistcut Snap-Off Bone Screw

Device Description:

MetaFix™ LS Locking Screws

The screws are fully threaded and self-tapping with a threaded head to lock into Merete Locking plates. Locking screws/plates incorporate a screw-to-plate locking feature which creates a locked, fixed angle construction to hold fracture or osteotomy reduction. The screws are made of titanium (ASTM F-136) and are available in the lengths from 12 mm to 32 mm (Ø3.0 mm), 12 mm to 48 mm (Ø3.5 mm) and 10 mm to 48 mm (Ø3.8 mm).

Merete® Cannulated PCS



The Merete® Cannulated PCS screw is a partly threaded, self-tapping, self-drilling and cannulated compression screw. The screws are made of titanium (ASTM-F136) and are available in the lengths from 12 mm to 48 mm (Ø3.0 mm). The wrench type of the screw is a torx socket.

Merete® CS Cortical Screws

The Merete® CS Cortical Screw is fully or partly threaded and self-tapping. The screws are made of titanium (ASTM-F136) and are available in the lengths from 10 mm to 40 mm (Ø3.0 mm or Ø3.5 mm). The wrench type of the screw is a torx socket.

Merete® Cannulated HCS

The Merete® Cannulated HCS screw is a partly threaded, self-tapping, self-drilling and cannulated headless compression screw. The screw is featured with a sinkable threaded head. The thread pitch of the shaft and the head are different to achieve a better compression. The screws are made of titanium (ASTM F-136) and are available in the lengths from 12 mm to 40 mm (Ø3.0 mm), 20 mm to 60 mm (Ø4.3 mm). The wrench type of the screw is a torx socket.

DuoThread™ Scarf Screws

The DuoThread™ Scarf screw is a partly or fully threaded, cannulated compression screw. The compression is obtained through a different thread pitch at the shaft and the head of the screw. The screws are made of titanium (ASTM-F136) and are available in the lengths from 10 mm to 34 mm (Ø3.0 mm). The wrench type of the screw is a torx socket.

TwistCut™ Snap-Off Screws

The TwistCut™ Snap-Off screw is self-tapping and self-drilling. The screw has a shank to chuck it into a K-Wire pistol, which is cut off when the screw head hits the cortex. The screws are made of titanium (ASTM-F136) and are available in the lengths from 11 mm to 14 mm (Ø2.0 mm).

Indications for Use

Indications for use include fixation of fractures. For specific screw indications please see below.

MetaFix™ LS Locking Screws

- for adult and pediatric patients
- in combination with Merete Locking Plates
- Fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulna, fibula, metacarpals, metatarsals
- Hallux Valgus osteotomy correction, middle hand and middle foot bones and particular in osteopenic bone

Merete® Cannulated PCS

- for adult and pediatric patients
- Fixation of fresh fractures
- Revision procedures
- Joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes

Merete® CS Cortical Screws

- for adult and pediatric patients
- Fixation of fresh fractures
- Revision procedures



- Joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes

Merete® Cannulated HCS

- Fixation of fractures and reconstruction of various bones
- Osteotomies in the foot (as Hallux Valgus) or hand
- Athrodesis in hand, foot or ankle surgery
- Fixation of bone fragments in long bones or small bone fractures

DuoThread™ Scarf Screws

- Small bone fracture fixation
- Fixation and stabilization of bones of the feet
- Osteotomies (Scarf-Osteotomy, Chevron-Austin Osteotomy, Akin-Osteotomy, Closing Wedge Osteotomy)
- Fusion (MPG-Athrodesis)
- Fixation of almost all common osteotomies of the first metatarsal

TwistCut™ Snap-Off Screws

- Fixation of fractures and reconstruction of bones
- Fixation of small bone fragments
- Mono cortical fixation
- Osteotomies (Weil-Osteotomy)
- Fracture fixation in the foot and hand

Comparison of technological characteristics with the predicate devices:

The basic technological characteristics of the screws named in the device description are the same as used for the predicate devices. Those characteristics contain the diameter, length, thread, pitch, amount of cutting flutes and if applicable (depending on the screw type) cannula diameter. The titanium material is also the same as used for the predicate devices and is in accordance to the specification given in ASTM-F136.

Differences in technological characteristics, caused by a change in the screwdriver screw-head interface, were evaluated by mechanical testing in accordance with ASTM F543 *Standard specification and Test Methods for Metallic Bone Screws*. Those tests included driving torque and torsional testing. Since all other mechanical specifications are the same as used for the predicate devices, the screws are considered to fulfil all defined criteria according to ASTM F543.

Further the screws are in sterile packaging. The sterilization process was validated according to current standards as well as the packaging system to protect the screws and ensure them to remain sterile.

All products have successfully passed the tests. All screws named in the device description have hereby been proven to be mechanically as good as or better than the predicate devices.

Substantial Equivalence:

The MetaFix™ LS Locking Screws, Merete® Cannulated PCS, Merete® CS Cortical Screws, Merete® Cannulated HCS, DuoThread™ Scarf Screws and TwistCut™ Snap-Off Screws have passed all defined criteria and have performed as well or better than the predicate devices and are therefore considered substantially equivalent to the cleared predicate devices.