Merete GmbH
Paul Munch
Head of Regulatory Affairs
Alt-Lankwitz 102
Berlin, 12247
Germany

October 23, 2017

Re: K172213
Trade/Device Name: MECRON Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 27, 2017
Received: October 2, 2017

Dear Mr. Munch:

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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172213

Device Name

MECRON™ Cannulated Screw System

Indications for Use *(Describe)*

The MECRON™ Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device.

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:

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"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:	27th July 2017
Submitted by:	Merete GmbH Alt-Lankwitz 102 12247 Berlin, Germany
Contact Person:	Merete GmbH Paul Münch (Head of Regulatory Affairs) Alt-Lankwitz 102 12247 Berlin, Germany Phone: +49-30 779980-181 Fax: +49-30 779980-177
Device Name:	**MECRON™ Cannulated Screw System**
Regulation/ Classification Names:	888.3040 Smooth or threaded metallic bone fixation fastener 888.3030 Single/ multiple metallic bone fixation appliances and accessories
Device Product Code:	HWC, HTN
Proposed Regulatory Class:	Class II

Legally marketed Devices to which substantial Equivalence is claimed:

K151418 Monster Screw System, Paragon 28

Reference devices:

K014154 VILEX/DUVAL/ORTHEX Cannulated Bone Screw, Model F20-xx-00

Device Description:

The MECRON™ Cannulated Screw System consists of headed and headless bone screws and corresponding washers. The screws are offered in diameters from 2.0mm thru 7.0mm (in 0.5 mm increments) and overall lengths from 8 mm (for smaller diameters) thru 120 mm (for larger diameters). The cannulated screws have self-tapping and self-drilling features and are manufactured from medical grade titanium alloy (per DIN EN ISO 5832-3 and ASTM F136).

Indications for Use

The MECRON™ Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device.

Comparison of technological characteristics with the predicate devices:
Merete has conducted mechanical analysis and functional worst case tests to demonstrate that the MECRON™ Cannulated Screw System has the mechanical properties necessary to perform as well or better than the predicate device and the reference device. These tests have been performed in accordance with ASTM F543-13. The MECRON Cannulated Screws have successfully passed all tests within the mechanical verification and have been proven to be mechanically as good as or better than the predicate device.

There are no differences in sterilization method or material in comparison to the predicate device. Sterilization has to be performed according to common valid standards as well as the material is specified according to common valid standards.

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

Substantial Equivalence:
The MECRON™ Cannulated Screw System has passed all defined criteria, has performed as well or better than the predicate device and is therefore considered substantially equivalent to the cleared predicate device.