DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 28, 2015

Merete Medical GmbH
% Mr. Matthias Möllmann
Senior Vice President
Merete Medical, Incorporated
4 Crotty Lane, Suite 118
New York International Plaza
New Windsor, New York 12553

Re: K151762
Trade/Device Name: PediatrOS™ RigidTack™/FlexTack™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, OBT
Dated: December 8, 2015
Received: December 11, 2015

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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic 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): K151762

Device Name: PediatrOS™ RigidTack™ / FlexTack™

Indications for Use:

The PediatrOS™ RigidTack™ / FlexTack™ bone staples are indicated for pediatric patients (children/ adolescents) with angular deformities or leg length discrepancies. Therefore PediatrOS™ RigidTack™ / FlexTack™ is intended to redirect the angle of growth of long bones and to correct leg length discrepancies by inhibition of longitudinal growth of the physis (growth plate) in growing children and adolescents.

Specific pediatric conditions/diseases for which the devices will be indicated include:

- Valgus, varus, or flexion, extension, deformities of the knee (femur and/or tibia)
- Valgus or varus deformities of the elbow (humerus)
- Leg length discrepancies

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness Information

as required by 21 CFR 807.92

Date Prepared:	04th December 2015
Submitted by:	Merete Medical GmbH Alt-Lankwitz 102 12247 Berlin, Germany
Contact Person:	Matthias Möllmann Senior Vice President Merete Medical, Inc. 4 Crotty Lane – Suite 118 New York International Plaza New Windsor, NY 12553 Phone: +49 163 06219832 E-Mail: mmoellmann@merete-medical.com
Device Name:	**PediatrOS™ RigidTack™/FlexTack™**
Common Name:	Bone Staples
Classification Names:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888-3030
Device Product Code:	JDR
Subsequent Product Code:	OBT
Proposed Regulatory Class:	Class II

Legally marketed Devices to which substantial Equivalence is claimed:

K031493	Guided Growth Plate, UNIVERSITY OF UTAH/SCHOOL OF MEDICINE
-	Blount Zimmalloy staple, Zimmer Inc. Warsaw, Indiana

Device Description:

PediatrOS™ RigidTack™

The PediatrOS™ RigidTack™ bone staples are used to correct leg length discrepancies through (dual) epiphysiodesis of long bones. The PediatrOS™ RigidTack™ has a trapezoidal shape which allows the staples to fit well to the epiphyseal bone. The staples are made from titanium alloy TiAl6V4 ELI and are available in several sizes, so they can be used for children of various age groups (before reaching skeletal maturity). The jagged surfaces of the staples' legs help secure it into the bone to prevent loosening. The staples have cannulated legs to facilitate placement through K-wires. In order to achieve a stiff mechanical behavior, the staples are equipped with a support strut. Female threads, built in the cannulated legs, help to remove the staples with threaded K-wires and the appropriate explantation instruments.

PediatrOS™ FlexTack™

The PediatrOS™ FlexTack™ bone staples are used to correct axial deformities through hemi-epiphysiodesis of long bones. The PediatrOS™ FlexTack™ has a trapezoidal shape which allows the staples to fit well to the epiphyseal bone. The staples are made from titanium alloy TiAl6V4 ELI and are available in several sizes, so they can be used for children of various age groups (before reaching skeletal maturity). The jagged surface of the staples' legs help secure it into the bone to prevent loosening. The staples have cannulated legs to facilitate placement through K-wires as well as a flexible middle part which can be bent in vivo by the strength of bone growth permitting successive growth delay. Female threads, built in the cannulated legs, help to remove the staples with threaded K-wires and the appropriate explantation instruments.

Indications for Use

The PediatrOS™ RigidTack™ / FlexTack™ bone staples are indicated for pediatric patients (children/ adolescents) with angular deformities or leg length discrepancies. Therefore PediatrOS™ RigidTack™ / FlexTack™ is intended to redirect the angle of growth of long bones and to correct leg length discrepancies by inhibition of longitudinal growth of the physis (growth plate) in growing children and adolescents.

Specific pediatric conditions/diseases for which the devices will be indicated include:

- Valgus, varus, or flexion, extension, deformities of the knee (femur and/or tibia)
- Valgus or varus deformities of the elbow (humerus)
- Leg length discrepancies

Comparison of technological characteristics with the predicate devices:

In order to demonstrate that the PediatrOS™ RigidTack™ / FlexTack™ bone staples have the mechanical properties necessary to perform as well as or better than the predicate devices, Merete has conducted mechanical analysis and functional worst-case tests. Those tests were stipulated by the optimatized design of the staple legs compared to the Blount Zimmalloy staple and the differences in the mechanism of growth following compared to the guided growth plate. The PediatrOS™ FlexTack™ has a flexible bending zone in contrast to a rigid plate with screw holes that allow screw displacement in distal-proximal direction in the guided growth plate. Therefore the following tests have been performed:

- Mechanical strength
- Stiffness
- Mechanical behavior
- Fixation into the bone

Those tests have demonstrated, that the mechanical strength is as high or higher than the strength of the predicate device. The stiffness is comparable to both predicate devices, too. The mechanical behavior comparison illustrated that the flexible bending zone in FlexTack™ deforms under small loads as intended and allows larger opening angles than physiological possible. A secure fixation into the bone was proven. If applicable the tests were performed according to valid standards as ASTM-F564-10(2015).

All products have successfully passed the tests. The PediatrOS™ RigidTack™ / FlexTack™ bone staples have hereby been proven to be mechanically as good as or better than the compared predicate devices.

Substantial Equivalence:

The PediatrOS™ RigidTack™ / FlexTack™ bone staples have passed all defined criteria, have performed as well or better than the predicate devices and are therefore considered substantially equivalent to the cleared predicate devices.