October 17, 2018

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

Re: K181026
Trade/Device Name: OsteoBridge™ IDSF System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 14, 2018
Received: September 17, 2018

Dear Mr. Münch:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.10.17 17:32:26 -04'00'

For: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181026

Device Name
OsteoBridge IDSF System

Indications for Use *(Describe)*

- Long-term stabilization of major bone defects resulting from
  - o Radical bone loss due to tumors and/or metastases
  - o Bone resections following tumors and/or metastases
- For use only in the diaphyseal region of humerus, tibia and femur

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.

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510(k) Summary of Safety and Effectiveness

Information as required by 21 CFR 807.92

Date Prepared:	09th October 2018
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
Trade Name:	OsteoBridge™ IDSF System
Common Device Name:	Intramedullary Fixation System
Classification Names:	Intramedullary fixation rod (21 CFR 888.3020)
Device Product Code:	HSB
Proposed Regulatory Class:	Class II

Legally marketed Devices to which substantial Equivalence is claimed:

Predicate Devices:	K142451	OsteoBridge™ IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System
Reference Devices:	K101939	OSTEOBRIDGE™ IKA INTRAMEDULLARY KNEE ARTHRODESIS ROD FIXATION SYSTEM

Device Description:

The OsteoBridge™ IDSF System is intended to be used in the management of segmental diaphyseal bone loss secondary to radical bone loss and/or resection due to tumors in either humerus, tibia or femur in oncology patients. The modular system includes a spacer made of two cylindrical half-shells that clamp over the ends of two intramedullary nails with eight screws. Spacers and intramedullary nails of different sizes can be selected to accommodate varying intramedullary canal diameters and different bone defect sizes. If the defect size is larger than 70 mm, two spacers may be connected with a spacer connector. The nails can be used non-cemented and cemented. All components of the OsteoBridge™ IDSF System are manufactured from Ti6Al4V ELI titanium alloy according to ASTM F 136.

Indications for Use:

- Long-term stabilization of major bone defects resulting from
    - Radical bone loss due to tumors and/or metastases
    - Bone resections following tumors and/or metastases
- For use only in the diaphyseal region of humerus, tibia and femur

Comparison of technological characteristics with the predicate devices:

All implants of the OsteoBridge™ IDSF System are delivered sterile now. Some implants of the predicate device had to be sterilized by the operator prior to use. The change of the delivery form of the implants results in the launch of reuseable trial components, which are offered in individual trays for each bone application (humerus, tibia and femur). The reducing bushings of the predicate device have been removed in the new system. The connector mechanism of the intramedullary rods has been adapted to the inner geometry and diameter of the matching spacer. All connecting mechanism surfaces are smooth instead of blasted.

Clinical and non-clinical data:

The change of the delivery form from non-sterile to sterile is performed according to the validated sterilization processes. The packaging for the sterile implants has been chosen according to the packaging validation test per DIN EN 22248:1993-02 to verify robustness of packaging. The package containing the worst-case device showed that the packaging and device remained undamaged after the test. The trial implants are delivered in a tray, anodized blue and lasered with “DO NOT IMPLANT”, so they cannot be mismatched with the sterile implants. The improvement in the connector mechanism and the surface of the devices has been tested in a dynamic bending test per ASTM F1264-16 as well as in a static torsion test. Both tests showed equivalent fatique limits and torsional strength.

Merete has conducted mechanical analysis and functional worst case tests to demonstrate that the OsteoBridge™ IDSF System has the mechanical properties necessary to perform as well or better than the predicate device. These tests have been performed in accordance with ASTM F1264-16 *“Standard Specification and Test Methods for Intramedullary Fixation Devices”.* The OsteoBridge™ IDSF System 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.

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

Substantial Equivalence:

The wording of the Indications for Use has been changed, but the modifications neither change the intended use of the subject device nor affect the safety and effectiveness of the device when used as labeled. The content remained the same – respectively the subject device is used for 3 bone applications in the event of bone loss due to tumors in oncology patients. The OsteoBridge™ IDSF 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.