implantcast GmbH
% Dave Mcgurl
Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

March 25, 2019

Re: K181778
Trade/Device Name: MUTARS Proximal Femur Replacement System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO
Dated: July 3, 2018
Received: July 3, 2018

Dear Dave Mcgurl:

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,

Daniel S. Ramsey -S
2019.03.25 16:08:20 -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K181778

Device Name

MUTARS® Proximal Femur Replacement System

Indications for Use *(Describe)*

The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Proximal Femur System is intended to for uncemented use in total hip arthroplasty for the following indications:

- Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
- Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of this prosthesis is generally only indicated in skeletally mature patients

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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"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

Device Trade Name: MUTARS® Proximal Femur Replacement System

Manufacturer:
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Germany

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Date Prepared: March 21, 2019

Common Name: Proximal Femur Replacement

Classification:
21 CFR §888.3353
21 CFR §888.3390

Class: II

Product Codes: MEH, LZO,

Primary Predicate Device: Stryker GMRS Proximal Femoral Replacement System (K965164, K023087)

Reference Predicate: Ecofit Hip System (K163577)

Indications for Use:
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Proximal Femur System is intended to for uncemented use in total hip arthroplasty for the following indications:

- Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
- Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of this prosthesis is generally only indicated in skeletally mature patients.

Device Description:
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system, which combines the offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient. The MUTARS® Proximal Femur Replacement System includes the MUTARS® Proximal Femur System. The MUTARS® Proximal Femur System is manufactured of $TiAl_6V_4$ and includes the proximal femur, femoral stem, stem extension piece, connecting part, and screws. The MUTARS® Proximal Femur Replacement System can be used as a total hip system with previously cleared (K163577) modular cobalt chrome femoral head, Ecofit® uncemented titanium alloy acetabular cup and polyethylene liner.

Performance Testing:
All necessary testing has been performed for the worst-case configuration of the MUTARS® Proximal Femur Replacement System to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of finished devices. The performance of the MUTARS® Proximal Femur Replacement System was characterized through the following tests:

- Construct fatigue
- Corrosion
- Range of Motion
- Modular Disassembly

Substantial Equivalence:
The MUTARS® Proximal Femur Replacement System is substantially equivalent with respect to materials, indications, function and performance to the Stryker GMRS Proximal Femoral Replacement System (K965164, K023087).