implantcast, GmbH
% Lindsay Kleinwaks
Associate, Regulatory Affairs
Mcra, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20005

October 16, 2020

Re: K200045
Trade/Device Name: MUTARS Cemented Femoral Stems
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, KWY
Dated: September 16, 2020
Received: September 16, 2020

Dear Lindsay Kleinwaks:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, M.S.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K200045

Device Name
MUTARS® Cemented Femoral Stems

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 for cemented and uncemented use in total hip arthroplasty or hemiarthroplasty 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 the 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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5. 510(K) SUMMARY

Manufacturer:	implantcast GmbH Lueneburger Schanze 26 21614 Buxtehude Germany
Contact:	Ms. Juliane Höppner Phone: +49 4161 744-135 Fax: +49 4161 744-200 j.hoeppner@implantcast.de
Prepared By:	Lindsay Kleinwaks, Ph.D. MCRA, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: 202.552.5833 lkleinwaks@mcra.com
Date Prepared:	January 8, 2019
Device Trade Name:	MUTARS® Cemented Femoral Stem
Device Class and Common Name:	Class II, Femoral Stem
Classification:	21 CFR §888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis – Class II
Product Codes:	MEH, LZO, KWY

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 for cemented and uncemented use in total hip arthroplasty or hemiarthroplasty 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 the prosthesis is generally only indicated in skeletally mature patients.

Device Description:

The purpose of this Traditional 510(k) is to expand the MUTARS® Proximal Femur System with a line extension to the existing cementless femoral stems. The new stems are intended for cemented applications.

Predicate Devices:

MUTARS® Proximal Femur System (K181778)

Substantial Equivalence:

The MUTARS® Cemented Femoral Stems are substantially equivalent to the predicate device system, the MUTARS® Proximal Femur Replacement System with respect to intended use and design.

Performance Testing:

All necessary testing has been performed for the worst-case MUTARS® Cemented Femoral Stems to assure substantial equivalence to its predicate and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of the finished device. The following testing was conducted to characterize the devices:

- Distal Stem Fatigue Testing (ISO 7206-4)
- Particle Analysis

Conclusions: The MUTARS® Cemented Femoral Stems possess the same intended use and technological characteristics as the predicate device. As such, the MUTARS® Cemented Femoral Stems are substantially equivalent for the intended use.