October 30, 2024

Implantcast, GmbH
% Hannah Irwin
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: K240391
Trade/Device Name: MUTARS® femoral stem cemented 160 mm and 200 mm
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: LZO, KWY

Dear Hannah Irwin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 24, 2024. Specifically, FDA is updating this SE Letter to include the additional product code KWY as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Limin Sun, Ph.D., OHT6: Office of Orthopedic Devices, at 301-796-7056 or Limin.Sun@fda.hhs.gov.

Sincerely,

Limin Sun -S

Limin Sun, Ph.D.
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

October 24, 2024

Implantcast, GmbH
% Hannah Irwin
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: K240391
Trade/Device Name: MUTARS® femoral stem cemented 160 mm and 200 mm
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: LZO
Dated: September 26, 2024
Received: September 25, 2024

Dear Hannah Irwin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Limin Sun -S

Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240391

Device Name
MUTARS® femoral stem cemented 160 mm and 200 mm

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 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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PRAStaff@fda.hhs.gov

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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:	Ms. Hannah Irwin MCRA, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: 202.552.5820 hirwin@mcra.com
Date Prepared:	October 22, 2024
Device Trade Name:	MUTARS® femoral stem cemented 160 mm and 200 mm
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
Product Codes:	LZO, KWY
Indications for Use:	The indications for use for the proposed MUTARS® femoral stem cemented 160 mm and 200 mm are as follows: 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 this prosthesis is generally only indicated in skeletally mature patients.

Device Description: The purpose of this Traditional 510(k) is to expand the MUTARS® Cemented Femoral Stems and MUTARS® Proximal Femur Replacement System with a line extension to the existing stems. The new stems are available with longer lengths (160 and 200mm).

Primary Predicate Device: MUTARS® Cemented Femoral Stems (K200045)

Additional Predicate Device: MUTARS® Proximal Femur Replacement System (K181778)

Substantial Equivalence: The MUTARS® femoral stem cemented 160 mm and 200 mm is substantially equivalent to the hip stems of the legally marketed predicate device systems, the implantcast MUTARS Cemented Femoral Stems and 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® femoral stem cemented 160 mm and 200 mm to assure substantial equivalence to the predicates 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 device:

- Distal Stem Fatigue Testing (ISO 7206-4)

Conclusions: The MUTARS® femoral stem cemented 160 mm and 200 mm subject to this submission possess the same intended use and technological characteristics as the predicate device system components. All performance testing conducted for the MUTARS® femoral stem cemented 160 mm and 200 mm met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the MUTARS® femoral stem cemented 160 mm and 200 mm is substantially equivalent to the predicate devices for the intended use.