March 6, 2025

Medacta International S.A.
% Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K241767
Trade/Device Name: Versacem Acetabular Shell and Double Mobility HC Liners
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: February 7, 2025
Received: February 7, 2025

Dear Christopher Lussier:

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.

Submission Number *(if known)*

K241767

Device Name

Versacem Acetabular Shell and Double Mobility HC Liners

Indications for Use *(Describe)*

Versacem is designed for use in total hip arthroplasty, for selected primary or revision surgery. Total hip arthroplasty is indicated in the following cases:
• Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis or congenital hip dysplasia.
• Avascular necrosis of the femoral head.
• Acute traumatic fracture of the femoral head or neck.
• Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty.

Versacem is also recommended when dislocation prevention is the main driver for the prosthesis choice and the acetabular bone quality is damaged, as in the following cases:
• Elderly patients or poor bone quality.
• Revision for recurrent dislocation in elderly patients with poor bone quality.
• Patients treated with radiotherapy or chemotherapy.

Versacem is intended for cemented use only.

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.

510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: June 18, 2024
Date Revised: February 07, 2025

II. Device

Device Proprietary Name:	Versacem Acetabular Shell and Double Mobility HC Liners
Common or Usual Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Primary Product Code	LZO
Regulation Number:	21 CFR 888.3353
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- NOVAE® Stick Dual Mobility Acetabular Cup, K111572, Serf

Reference predicate devices:

- Double Mobility HighCross® highly crosslinked UHMWPE, K092265, Medacta International SA
- Double Mobility HighCross® highly crosslinked UHMWPE, K131458, Medacta International SA
- Double Mobility HighCross highly crosslinked UHMWPE Liners, K143453, Medacta International SA
- Medacta Bipolar Head, K091967, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the Versacem Acetabular Shell and to add two new sizes of the compatible Double Mobility HC Liners previously cleared within K092265, K131458 and K143453.
The Versacem Acetabular Shell implants and the Double Mobility HC liners are sterile, individually packaged, implantable medical devices intended to be used in Total Hip Arthroplasty.

The devices subject of this submission are:

- Versacem Acetabular Shell from size ∅40 to size ∅56;
- Double Mobility HC liner Ø22.2/DMAZ;
- Double Mobility HC liner Ø28/DMC.

V. Indications for Use

Versacem is designed for use in total hip arthroplasty, for selected primary or revision surgery. Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis or congenital hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty.

Versacem is also recommended when dislocation prevention is the main driver for the prosthesis choice and the acetabular bone quality is damaged, as in the following cases:

- Elderly patients or poor bone quality.
- Revision for recurrent dislocation in elderly patients with poor bone quality.
- Patients treated with radiotherapy or chemotherapy.

Versacem is intended for cemented use only.

VI. Comparison of Technological Characteristics

The subject Versacem Acetabular Shell and the predicate device NOVAE® Stick Dual Mobility Acetabular Cup (K111572) are substantially equivalent with respect to the following characteristics:

- General Design;
- Articular surface;
- Cementation;
- Material;
- Biocompatibility;
- Device usage
- Packaging

The subject Versacem Acetabular Shell and the predicate device NOVAE® Stick Dual Mobility Acetabular Cup (K111572) differ with respect to the following characteristics:

- Range of sizes;
- Shelf-life;
- Sterilization method.

Discussion

The slight difference between subject and predicate devices range of sizes do not pose any new risk in terms of safety and performance as evaluated in the bench testing.
The subject device shelf-life does not affect in any way its safety and performance, as it is shared with the predicate device Medacta Bipolar Head (K091967) and in general with the majority of Medacta products cleared in US. The Medacta Bipolar Head (K091967) is substantially equivalent to the subject device in terms of manufacturing material and main steps of the production process.
Finally, the subject device sterilization method do not arise any new risk in terms of safety and performance as it is fully validated.

The subject Double Mobility HC liners are substantially equivalent to the predicate devices Double Mobility HC Liners (K092265; K131458; K143453) with respect to the following characteristics:

- Design;
- Articular Surface;
- Material;
- Biocompatibility;
- Device Usage;
- Packaging;
- Shelf-life;
- Sterilization method.

The subject Double Mobility HC liners differ from the predicate devices Double Mobility HC Liners (K092265; K131458; K143453) with respect to the following characteristics:

- Range of sizes.

Discussion

The difference between subject and predicate devices range of sizes do not pose any new risk in terms of safety and performance as the inner diameter of subject and predicate devices is the same. The difference in the outer diameter between subject and predicate device do not pose any new risk in terms of safety and performance as evaluated in the bench testing.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validations and tests are provided in support of the substantial equivalence determination.

Nonclinical Studies

DESIGN VALIDATION

- Versacem Acetabular Shell and double Mobility HC Liner Design Validation

PERFORMANCE TESTING

- Versacem Acetabular Shell and Double Mobility HC Liners – Wear Test
- Versacem Acetabular Shell – Range of Motion Evaluation
- Versacem Acetabular Shell – Fatigue Test
- Double Mobility HC Liner – Pull-off and Lever-out Tests
- Versacem Acetabular Shell – Evaluation of Jumping Distance
- Versacem Acetabular Shell – Evaluation of impingement risk

PYROGENICITY

Medacta International does not intend to label the subject devices as non-pyrogenic or pyrogen free. Control of pyrogenicity is validated through the following primary test methods on all identified representative devices as part of their initial validation prior to submission:

1. Quantification of bacterial endotoxin units (EU) on the device surface after final cleaning and sterilization using the bacterial endotoxin test (LAL test) on the basis of a measured colour-producing reaction proportional to the interaction of Limulus amebocyte lysate (LAL) and endotoxin according to ISO11737-3 and European Pharmacopoeia §2.6.14 (which is harmonized with USP chapter <85> and USP <161>)
2. In-vivo evaluation of pyrogenicity in rabbit, per USP <151>, in conjunction with biocompatibility studies.

BIOCOMPATIBILITY assessment

SHELF-LIFE evaluation

VIII. Conclusion

The information provided above supports that the subject devices are substantially equivalent to the predicate devices.