October 31, 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: K250338
Trade/Device Name: MSS - Humeral reverse liners extension
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: October 1, 2025
Received: October 1, 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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.10.31 13:53:20 -04'00'

Farzana Sharmin, PhD
Assistant Director
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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)*

K250338

Device Name

MSS - Humeral reverse liners extension

Indications for Use *(Describe)*

The Reverse Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint.
The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.
The glenoid baseplate is intended for cementless application with the addition of screws for fixation.
The humeral stems are intended for cemented or cementless use.
The Glenoid Reconstruction System baseplate is intended for cementless application with the addition of polyaxial screws for primary stability. A Glenoid Reconstruction System central screw can be used to provide additional fixation.

The Reverse Shoulder Prosthesis - Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with grossly deficient rotator cuff shoulder joint with severe arthropathy. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral short stem is intended for cementless use. The Glenoid Reconstruction System baseplate is intended for cementless application with the addition of polyaxial screws for primary stability. A Glenoid Reconstruction System central screw can be used to provide additional fixation.

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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Phone: 901-203-3470
Date Prepared: October 31, 2025

II. Device

Device Proprietary Name:	MSS - Humeral reverse liners extension
Common or Usual Name:	Shoulder prosthesis, reverse configuration
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Primary Product Code	PHX
Regulation Number:	21 CFR 888.3660
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Medacta Shoulder System, K170452, Medacta International SA

Additional Predicate devices

- Glenoid Reconstruction System – Full Wedge Baseplate, K231911, Medacta International SA
- DELTA XTEND Reverse Shoulder System, K062250, DePuy Orthopaedics, Inc.

Reference device:

- GMK-SPHERE Tibial inserts FLEX Tibial Insert CR and Resurfacing Patella made of E-CROSS (Vitamin E Highly Crosslinked UHMWPE), K202022, Medacta International SA

IV. Device Description

The MSS - Humeral reverse liners extension is a Medacta Shoulder System line extension aiming to include the following new implants:

- Humeral reverse liners made of Vitamin E Highly Crosslinked polyethylene (E-Cross); and
- Humeral reverse constrained liners available both in Highly Crosslinked Polyethylene (HCPE) and Vitamin E Highly Crosslinked polyethylene (E-Cross).

The MSS - Humeral reverse liners extension implants are intended to be used in the reverse configuration only, in order to replace the humeral side of the gleno-humeral joint. They are available in 4 articular surface diameters and 3 heights. The subject MSS - Humeral reverse liners have been designed to be coupled with Medacta Shoulder System humeral reverse metaphysis and to provide an articular surface for the glenosphere.

The subject liners are implantable devices provided individually packed, sterile and single-use.

V. Indications for Use

The Reverse Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint.
The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.
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The Reverse Shoulder Prosthesis - Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with grossly deficient rotator cuff shoulder joint with severe arthropathy. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral short stem is intended for cementless use. The Glenoid Reconstruction System baseplate is intended for cementless application with the addition of polyaxial screws for primary stability. A Glenoid Reconstruction System central screw can be used to provide additional fixation.

VI. Comparison of Technological Characteristics

The subject MSS - Humeral reverse liners extension implants and Medacta primary predicate devices (K170452) are substantially equivalent with respect to the following characteristics:

- Articular surface diameters;
- Inclination;
- Heights;
- Metaphysis coupling;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and

- Sterilization.

The subject MSS - Humeral reverse liners extension implants differ from Medacta primary predicate devices (K170452) with respect to:

- Jump height of constrained liners; and
- Material.

Discussion

The different jump height of the subject constrained liners does not raise any different questions of safety and effectiveness since it is included within the range of the additional predicate device, DELTA XTEND Reverse Shoulder System (K062250).

The E-Cross material of the subject liners does not raise any different questions of safety and effectiveness since it is shared with the reference device, GMK-Sphere E-Cross Tibial inserts (K202022).

VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Mechanical Wear Test on the Medacta Shoulder System - Reverse with Humeral Reverse Liner Constrained
  - Lever-out strength of E-Cross Liner and Constrained Liner
  - Torsional strength of Humeral Reverse Liner
  - Humeral reverse liner constrained – Push-out strength assessment
  - Humeral reverse liner constrained – ROM assessment

- *BIOCOMPATIBILITY assessment*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the subject device is substantially equivalent to the predicate device.