



June 10, 2026

Medacta International, SA  
% Christopher Lussier  
Senior Director, Quality and Regulatory  
Medacta USA  
6386 Global Dr., Suite 101  
Memphis, Tennessee 38141

Re: K261016

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: March 27, 2026  
Received: March 27, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**FARZANA SHARMIN -S**

Farzana Sharmin, PhD

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

# Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261016

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Please provide the device trade name(s).

?

MSS - Humeral reverse liners extension

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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## 510(k) Summary

### I. Submitter

Medacta International SA  
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 Switzerland  
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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: March 27, 2026

### 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:

- MSS - Monobloc stem, K250644, Medacta International SA

Additional Predicate devices

- MSS - Humeral reverse liners extension, K250338, Medacta International SA

### IV. Device Description

The MSS - Humeral reverse liners extension is a Medacta Shoulder System line extension aiming to include implantable devices provided individually packed, EtO sterile and single-use, intended to be used in the reverse configuration only, in order to replace the humeral side of the gleno-humeral joint. Specifically, this submission aims at obtaining the clearance for the Humeral reverse constrained liners made of E-Cross (Ultra High Molecular Weight Polyethylene (UHMWPE) + vitamin E) and available with small or large metaphyseal coupling interface.

## 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.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

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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 the primary predicate devices (K250644) are equivalent with respect to the following characteristics:

- Coupling interface;
- Articular surface diameters;
- Inclination;
- Height;
- Material;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and
- Sterilization.

The subject MSS - Humeral reverse liners extension implants differ from the primary predicate devices (K250644) only with respect to the jump height.

### *Discussion*

The different jump height of the subject constrained liners does not raise any new issue of safety and effectiveness since it is equivalent to the one of the additional predicate devices cleared within K250338.

## VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Mechanical Wear Test worst case analysis
  - Static Lever-out strength comparative test
  - Push-out strength assessment rationale
  - Torsional strength assessment rationale
  - ROM assessment according to ASTM F1378-18e1
- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.
- *BIOCOMPATIBILITY assessment*
- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

**VIII. Conclusion**

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