



February 3, 2026

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

Re: K250644

Trade/Device Name: MSS - Monobloc stem

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: PHX, KWS, HSD

Dated: January 29, 2026

Received: January 29, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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) 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

Submission Number (if known)

K250644

Device Name

MSS - Monobloc stem

Indications for Use (Describe)

- **Reverse Shoulder Prosthesis**

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.

- **Anatomic Shoulder Prosthesis**

The Medacta Anatomic Shoulder Prosthesis is intended for use as a hemi or total shoulder replacement for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The humeral stems are intended for cemented or cementless use.

The Medacta Anatomic Shoulder Prosthesis - Short Humeral Diaphysis is indicated for hemi or total primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint and 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 for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The humeral short stem is intended for cementless use.

• Reverse Shoulder Prosthesis – monobloc stem

The reverse shoulder prosthesis using the standard monobloc stem 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 standard monobloc stem is intended for cementless use only. Two optional cortical bone screws should be used.

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 using the short monobloc stem 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 short monobloc stem is intended for cementless use only.

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.

• Anatomic Shoulder Prosthesis – monobloc stem

The anatomic shoulder prosthesis using the standard monobloc stem is intended for use as a hemi or total shoulder replacement. It is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The standard monobloc stem is intended for cementless use only. Two optional cortical bone screws should be used.

The anatomic shoulder prosthesis using the short monobloc stem is indicated for hemi or total primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint and 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 for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The short monobloc stem is intended for cementless 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.

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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, Medacta USA
Date Prepared: March 04, 2025
Date Revised: January 3rd, 2026

II. Device

Device Proprietary Name:	MSS – Monobloc stem
Common or Usual Name:	Shoulder prosthesis, reverse configuration
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Primary Product Code	PHX
Secondary Product Code	KWS, HSD
Regulation Number:	21 CFR 888.3660, 21 CFR 888.3690
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:

- FX V135™ Shoulder Prosthesis, K223801, FX Shoulder USA, Inc
- FX V135™ Shoulder Prosthesis, K213117, FX Shoulder USA, Inc
- Medacta Anatomic Shoulder Prosthesis, K170910, Medacta International SA
- Medacta Shoulder System Short Humeral Diaphysis, K180089, Medacta International SA
- Glenoid Reconstruction System – Full Wedge Baseplate, K231911, Medacta International SA
- Humeral Eccentric Reverse Metaphysis, K210207, Medacta International SA
- INHANCE Reverse Shoulder System, K212737, Depuy Ireland UC
- HUMELOCK II Cementless shoulder system, K130759, Fx Solutions

Reference devices:

- GMK-SPHERE Tibial inserts FLEX Tibial Insert CR and Resurfacing Patella made of E-CROSS (Vitamin E Highly Crosslinked UHMWPE), K202022, Medacta International SA
- Mpac 3D Metal implants – DMLS Technology, K202568, Medacta International SA

IV. Device Description

The MSS – Monobloc stem is a Medacta Shoulder System line extension including the following implantable, individually packed, sterile and single-use devices:

- Monobloc stem, 11 sizes available in both standard and short versions. Short version has been designed, as the standard version, made of Ti6Al7Nb with Ti+HA coating, but also made from Ti6Al4V powder through an additive manufacturing process;
- Monobloc stem spacer small and large;
- Monobloc stem double eccentric small and large;
- Monobloc stem spacer/double eccentric screw;
- Distal screws with lengths from 18 to 36 in 2mm steps;
- Humeral reverse liners small and large available both in UHMWPE highcross and UHMWPE + vitamin E;
- Humeral reverse metaphysis small concentric and eccentric.

V. Indications for Use

○ *Reverse Shoulder Prosthesis*

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.

○ *Anatomic Shoulder Prosthesis*

The Medacta Anatomic Shoulder Prosthesis is intended for use as a hemi or total shoulder replacement for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with

an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The humeral stems are intended for cemented or cementless use.

The Medacta Anatomic Shoulder Prosthesis - Short Humeral Diaphysis is indicated for hemi or total primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint and 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 for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The humeral short stem is intended for cementless use.

○ ***Reverse Shoulder Prosthesis – monobloc stem***

The reverse shoulder prosthesis using the standard monobloc stem 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 standard monobloc stem is intended for cementless use only. Two optional cortical bone screws should be used.

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 using the short monobloc stem 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 short monobloc stem is intended for cementless use only.

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.

○ ***Anatomic Shoulder Prosthesis – monobloc stem***

The anatomic shoulder prosthesis using the standard monobloc stem is intended for use as a hemi or total shoulder replacement. It is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The standard monobloc stem is intended for cementless use only. Two optional cortical bone screws should be used.

The anatomic shoulder prosthesis using the short monobloc stem is indicated for hemi or total primary total shoulder replacement in patients with an intact or repairable rotator cuff shoulder joint and 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 for the device to offer full function in vivo.

The glenoid component is intended for cemented application.

The short monobloc stem is intended for cementless use only.

VI. Comparison of Technological Characteristics

The subject and predicate devices (K170452, K170910, K180089, K210207, K223801 and K213117) are substantially equivalent with respect to the following characteristics:

- Monobloc stem design;
- Stem sizes;
- Stem fixation;
- Stem and liners inclination;
- Liners articular surface diameter;
- Liners and spacers height;
- Liners jump height;
- Double eccenters and metaphysis eccentricity;
- Coating, if applicable;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and
- Sterilization.

The subject devices differ from the predicate devices (K170452, K170910, K180089, K210207, K223801 and K213117) with respect to:

- Stem lengths;
- Stem coated area
- Stem suture hole;
- Liners coupling with the metaphysis;
- Metaphysis diameter;
- Spacers and double eccenters sizes; and
- 3D Metal short stem as well as E-Cross liners materials.

The subject distal screws are substantially equivalent to the predicate Humelock II Cementless Shoulder System – cortical screws (K130759) with respect to the main technological features.

Discussion

The subject monobloc stem lengths are partially different with respect to the predicate devices but this difference has no impact on safety and effectiveness since the subject devices' lengths is included in the range of Medacta predicate devices (K170452, K170910 and K180089).

The slightly different stem coated area between the subject and predicate devices does not raise any different questions of safety and effectiveness since the subject devices coated area percentage is within the range of Medacta predicate devices (K170452, K170910 and K180089).

The partially different suture holes of the subject monobloc stems respect to the predicate devices (K170452, K170910, K180089, K223801 and K213117) do not introduce any different questions with regards to safety and effectiveness since both the subject predicate devices have lateral and medial holes. The tabs on the subject humeral reverse liners small and large have the same objective of the peg on Medacta humeral reverse liners cleared within K170452 without raising any different questions of safety and effectiveness.

The subject small humeral reverse metaphysis diameter does not affect safety and effectiveness since it is in the range of the predicate device, INHANCE Reverse Shoulder System (K212737).

The availability of two different sizes of spacers and double eccenters is strictly related to the two different metaphysis diameters designed on the subject monobloc stem, thus it has not any impact on safety and effectiveness.

The 3D metal version of the short stem as well as the E-cross version of humeral reverse liners small and large do not affect safety and effectiveness since the materials as well as the manufacturing processes are shared with the reference devices cleared within K202568 and K202022, respectively.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

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:

Non-Clinical Studies

- *DESIGN VALIDATION*
 - Monobloc stem design validations
 - Small humeral reverse metaphysis: assessment of design and dimensions
 - Small humeral reverse metaphysis: coupling assessment
- *PERFORMANCE TESTING*
 - Lever-out strength of Humeral Reverse Liner - Small & Large
 - Push-out strength of Humeral Reverse Liner - Small & Large
 - Torsional strength of Humeral Reverse Liner - Small & Large
 - Mechanical fatigue test on 3D Metal monobloc humeral reverse stemmed construct
 - Mechanical fatigue test on 3D Metal monobloc humeral anatomic stemmed construct
 - Mechanical fatigue test on monobloc humeral reverse and anatomic stemmed construct

- Coupling strength of monobloc stem double eccentric
 - Monobloc stem ROM assessment according to ASTM F1378-18e1
 - Rationale for tensile and shear tests of the pyramidal net
 - Mechanical fatigue testing on humeral reverse stemmed constructs with small reverse metaphysis
 - Mechanical Wear Test on the Medacta Shoulder System - Reverse with Humeral Reverse Liner Constrained
 - Distal screw static tests
 - Mechanical fatigue test on distal screws for monobloc stem
 - Characterization report for Titanium + Hydroxyapatite double coating on monobloc stem in terms of roughness, thickness, porosity, sandblasting pollution and static tensile strength
 - Cross sectioned area of the Titanium + Hydroxyapatite implant surfaces of the Medacta monobloc stem
 - SEM pictures of the Titanium + Hydroxyapatite implant surfaces of the Medacta monobloc stem
 - XRD analyses comparing features of the Hydroxyapatite coating deposited on the Medacta monobloc stem and on planar samples
 - Rationale: Extension of the sizes for the humeral reverse metaphysis coating characterization
- *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.