Medacta International S.A.
% Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp St
Memphis, Tennessee 38118

November 9, 2023

Re: K231911
Trade/Device Name: Glenoid Reconstruction System - Full Wedge Baseplate
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 12, 2023
Received: October 16, 2023

Dear Chris 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.

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: 2023.11.09 17:53:11 -05'00'

Farzana Sharmin, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231911

Device Name
Glenoid Reconstruction System – Full Wedge Baseplate

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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, Sr. Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: June 28, 2023
Date Revised: November 9, 2023

II. Device

Device Proprietary Name:	Glenoid Reconstruction System – Full Wedge Baseplate
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 devices:

Primary predicate device

- The Univers Revers Augmented Modular Glenoid System, K193372, Arthrex

Additional predicate device

- Medacta Glenoid Reconstruction System, K213459, Medacta International SA
- Aequalis Perform Reversed, K161742, Wright Medical

Reference device

- Medacta Shoulder System, K170452, Medacta International SA

IV. Device Description

Glenoid Reconstruction System (GRS) Full Wedge baseplate is a Medacta Shoulder System line extension to provide a larger product offering.

It includes GRS Full Wedge baseplate and central screws, sterile implantable devices used to replace only the glenoid side of the gleno-humeral joint in a shoulder reverse configuration.

The GRS Full Wedge baseplate, intended for cementless application, is designed to be fixed into the glenoid bone by means of both a press-fit central post and Glenoid Polyaxial Screws. If desired, a GRS Central Screw can be used to provide additional stability.
The GRS Full Wedge baseplate is designed to provide an interface for glenosphere coupling.

The subject baseplate is available in two taper diameters (Ø24.5 and Ø27) with two different lengths (20 and 30 mm) of the central post and 4 full wedge options (10°, 15°, and 20°).
It is made of Ti6Al7Nb according to ISO 5832-11 and double coated with Ti coating according to ASTM F1580-18 and HA coating according to ASTM F1185-03.

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. 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.

VI. Comparison of Technological Characteristics

The subject and predicate devices (K193372, K213459, and K161742) are substantially equivalent with regards to the following characteristics:

- general design;
- angle correction (except the predicate K213459);

- fixation;
- biocompatibility;
- device usage;
- sterility;
- shelf-life; and
- packaging.

The subject implants differ from the predicate devices K213459 as follows:

- angle correction;

Discussion
Medacta International SA has not made any change to the indications for use, general design and shape, fixation, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.
Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the Glenoid Reconstruction System implants to the identified predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Glenoid Reconstruction System - Full Wedge Baseplate Design Validation

- *PERFORMANCE TESTING*
  - Fatigue testing on glenoid reconstruction system
  - Micromotion assessment on Glenoid reconstruction system Full Wedge Baseplate according to ASTM F2028-17
  - Range of Motion Assessment
  - Characterization Report “Y367” Titanium + “Osprovit” Hydroxyapatite double coating on GRS Glenoid baseplate component
  - Scanning electron microscopy pictures of the "Y367" Titanium + "Osprovit" HA implant surfaces of the GRS Glenoid baseplate
  - Cross sectioned area of “Y367” Titanium + “Osprovit” HA implant surfaces of the GRS Glenoid baseplate
  - Rationale comparison between features of the Hydroxyapatite Osprovit coating deposited on the Medacta GRS Glenoid baseplate and on planar samples made of Ti6Al7Nb, based on XRD analyses

- *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 evaluation*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the Glenoid Reconstruction Systems Full Wedge baseplate implants are substantially equivalent to the primary predicate device.