Medacta Inernational SA
Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

August 11, 2020

Re: K193175
Trade/Device Name: Lateralized Glenosphere
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, MBF
Dated: July 10, 2020
Received: July 13, 2020

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Michael Owens
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193175

Device Name
Lateralized Glenosphere

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 rotator cuff deficient 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.

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

Medacta International SA
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Contact Person: Stefano Baj, Regulatory Affairs and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: November 15, 2019
Date Revised: August 7, 2020

II. Device

Device Proprietary Name:	Lateralized Glenosphere
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:	HSD and MBF
Regulation Number:	21 CFR 888.3660 (Primary), 21 CFR 888.3690 and 21 CFR 888.3670
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate:
  - Glenosphere (Medacta Shoulder Reverse System), K170452, Medacta International SA;

- Reference Device:
  - Aequalis PerFORM Reversed, Aequalis PerFORM+ Reversed Glenoid, K161742, Tornier, Inc.

IV. Device Description

The Lateralized Glenosphere are line extensions to the Medacta Shoulder Reverse System (K170452) and are compatible with the other Medacta cleared products Threaded Glenoid Baseplate (K171058), Glenoid Polyaxial Non-Locking Screws (K181826) and the Short Humeral Stem (K180089).

The Lateralized Glenosphere implants subject of this submission are comprised of the following products (9 sizes):

- Size Ø 32: to be coupled with Medacta Glenoid Baseplate Ø 22 or Ø 24.5mm
- Size Ø 36: to be coupled with Medacta Glenoid Baseplate Ø 22 or Ø 24.5 or Ø27mm
- Size Ø 39: to be coupled with Medacta Glenoid Baseplate Ø 24.5 or Ø27mm
- Size Ø 42: to be coupled with Medacta Glenoid Baseplate Ø 24.5 or Ø27mm

The Lateralized Glenosphere implants are part of the Medacta Shoulder Reverse System. The Medacta Shoulder Reverse System consists of the following components:

- Humeral Diaphysis - Cemented;
- Humeral Diaphysis - Cementless;
- Humeral Reverse Metaphysis;
- Humeral Reverse HC Liner (also referred to as PE Liner);
- Glenoid Baseplate - Pegged;
- Glenoid Baseplate - Threaded;
- Glenosphere;
- Glenoid Polyaxial Locking Screw;
- Glenoid Polyaxial Non-Locking Screw;
- Reverse Metaphysis Screw; and
- Glenosphere Screw.

The glenosphere is attached to the glenoid baseplate and secured by means of a taper connection and a fastening screw.

The purpose of the current submission is to gain clearance for the Lateralized Glenospheres, whose center is more lateralized respect to Medacta predicate device Glenosphere (Medacta Shoulder Reverse System - K170452).
The new option of lateralization allows the surgeon to intraoperatively select the desired level of ROM and resulting joint tension based on the patient's anatomy.

The Lateralized Glenosphere is made of CoCrMo *ISO 5832-12 (Second Edition 2007-05-01) Implants For Surgery – Part 12: Wrought Cobalt- Chromium-Molybdenum Alloy [Including: Technical Corrigendum 1 (2008)]*, while the Glenosphere screw packed with the implant is made of Ti alloy (Ti-6Al-4V), enhanced with Type-II anodization, according to *ISO 5832-3:2016 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*.

The Lateralized Glenosphere implants are substantially equivalent to Medacta predicate device Glenosphere implants (K170452) and to competitor predicate device Aequalis PerFORM Reversed, Aequalis PerFORM+ Reversed Glenoid, K161742, Tornier, Inc.

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 rotator cuff deficient 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.

VI. Comparison of Technological Characteristics

The Lateralized Glenosphere and the main predicate device Glenosphere (cleared within Medacta Shoulder Reverse System) K170452, Medacta International SA share the following characteristics:

- indications for use;
- material of construction;
- sizes
- eccentricity of the COR (Center Of Rotation);
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Lateralized Glenosphere is technologically different from the main predicate device as follows:

- lateralization of the COR.

The subject Lateralized Glenosphere has the same technological characteristics of the Medacta predicate device Glenosphere (cleared within Medacta Shoulder Reverse System) K170452, with the only exception of the grade of lateralization of the COR, feature shared with the other predicate AEQUALIS™ REVERSED II Shoulder Prosthesis (K112144). This new option of lateralization allows the surgeon to intraoperatively select the desired level of ROM and resulting joint tension based on the patient's anatomy.

Biocompatibility testing conducted on the main predicate device for the same materials supports the biological safety of the Lateralized Glenosphere. Subject and predicate devices are manufactured from the following material: CoCrMo *ISO 5832-12 (Second Edition 2007-05-01) Implants For Surgery – Part 12: Wrought Cobalt- Chromium-Molybdenum Alloy [Including: Technical Corrigendum 1 (2008)]*, while the Glenosphere screw packed with the implant is made of Ti alloy (Ti-6Al-4V), enhanced with Type-II anodization, according to *ISO 5832-3:2016 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- Characterization Tests
  - Design Validation Report.
- Performance Tests
  - Micromotions Assessment In Reverse Configuration With A Lateralized Glenosphere: *ASTM F2028-17: Standards Test Methods For Dynamic Evaluation of Glenoid Loosening or Disassociation*;
  - Fatigue Test On Threaded Glenoid Reverse Construct With A Lateralized Glenosphere: *ASTM F1378-17 – Standard Specifications for Shoulder Prosthesis*; and
  - Rationale, Lateralized Glenosphere – Wear Assessment.
- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination; and
  - the subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the Lateralized Glenospheres are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The Lateralized Glenosphere implants are as safe and effective as the predicate devices Medacta standard Glenosphere cleared under Medacta Shoulder Reverse System K170452 (predicate device) and Tornier AEQUALIS^{TM} REVERSED II Shoulder Prosthesis (K112144).