Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 83118

March 26, 2021

Re: K210207
Trade/Device Name: Humeral Eccentric Reverse Metaphysis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, MBF
Dated: January 25, 2021
Received: January 26, 2021

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,

Michael Owens
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)*
K210207

Device Name
Humeral Eccentric Reverse Metaphysis

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 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.

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 Affairs Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: January 25, 2021
Date Revised: March 26, 2021

II. Device

Device Proprietary Name:	Humeral Eccentric Reverse Metaphysis
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 , MBF
Regulation Number:	21 CFR 888.3660 and 21 CFR 888.3670
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate:
  - Humeral reverse metaphysis (Medacta Shoulder Reverse System), K170452, Medacta International SA;

- Reference Device:
  - Delta Xtend™ Reverse Shoulder System, K120174, DePuy Orthopaedics, Inc.
  - Short Humeral Stem, K180089, Medacta International
  - Medacta Shoulder System – Long Stem Shoulder, K192967, Medacta International

IV. Device Description

The Humeral Eccentric Reverse Metaphysis is a line extension to the Medacta Shoulder Reverse System (K170452) and it is compatible with the other Medacta cleared products: Humeral Reverse PE Liner (K170452), Humeral Diaphysis (K170452), Short Humeral Diaphysis (K180089), Long Humeral Diaphysis (K192967).

The Humeral Eccentric Reverse Metaphysis implant subject of this submission is comprised of the following size: Diameter= Ø37.5mm Offset= 3mm.

The Humeral Eccentric Reverse Metaphysis 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;
- Lateralized Glenosphere
- Glenoid Polyaxial Locking Screw;
- Glenoid Polyaxial Non-Locking Screw;
- Reverse Metaphysis Screw; and
- Glenosphere Screw.

The Humeral Diaphysis and the Humeral Reverse Metaphysis (standard or eccentric) are intended to be assembled together by means of a cylindrical driven-fit coupling and tightened by the Reverse Metaphysis Screw. The Humeral Reverse HC Liner is intended to be coupled by means of an embedded clipping mechanism with the Humeral Reverse Metaphysis (standard or eccentric).

The purpose of the current submission is to gain clearance for the Humeral Eccentric Reverse Metaphysis.

The main body of Humeral Eccentric Reverse Metaphysis,is made of Ti alloy (Ti-6Al-4V), according to *ISO 5832-3:2016 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*.

The screw of the Reverse Metaphysis (standard or eccentric), packaged with main body, is made of Ti alloy (Ti-6Al-4V), according to *ISO 5832-3:2016 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*, enhanced with Type-II anodization.

The Humeral Eccentric Reverse Metaphysis, implant is substantially equivalent to Medacta predicate device Humeral reverse metaphysis (K170452) and to competitor predicate device Delta Xtend™ Reverse Shoulder System, (K120174) Depuy Orthopaedics, 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 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 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.

VI. Comparison of Technological Characteristics

The Humeral Eccentric Reverse Metaphysis and the main predicate device Humeral reverse metaphysis (cleared within Medacta Shoulder Reverse System) K170452, Medacta International SA share the following characteristics:

- indications for use;
- substrate material (Ti6Al4V);
- Humeral reverse construct:
- diameter;
- humeral reverse HC liner - Inclination
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Humeral Eccentric Reverse Metaphysis is technologically different from the main predicate device as follows:

- Connection between Metaphysis and Diaphysis (there is no reverse indexing pin)
- Numbers of Eyelets

- Coating (there is no coating)
- Size range

The subject Humeral Eccentric Reverse Metaphysis has the same technological characteristics of the Medacta predicate device Humeral Reverse Metaphysis (cleared within Medacta Shoulder Reverse System) K170452, with the only exception of the offset between Metaphysis and Diaphysis, feature shared with the other predicate Delta Xtend™ Reverse Shoulder System, K120174, DePuy Orthopaedics, Inc.
The biocompatibility of the Humeral Eccentric Reverse Metaphysis was evaluated based on using identical materials and manufacturing processes as a previously cleared device. The subject and predicate devices are manufactured from the following material: Ti alloy (Ti-6Al-4V), according to ISO 5832-3:2016 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy.

While the screw of the Reverse Metaphysis (standard or eccentric), packed with the main body is made of Ti alloy (Ti-6Al-4V), according to *ISO 5832-3:2016 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy* enhanced with Type-II anodization.

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
  - Static Torsion test
  - Rationale, Humeral Eccentric Reverse Metaphysis – Worst Case 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 Humeral Eccentric Reverse Metaphysis is 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 Humeral Eccentric Reverse Metaphysis implants are substantially equivalent to the predicate devices Medacta Humeral Reverse Metaphysis cleared under Medacta Shoulder Reverse System K170452 (predicate device).