Medacta International, SA
% Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
MEMPHIS, TN 38118

March 25, 2020

Re: K192967
Trade/Device Name: Medacta Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, KWS, KWT
Dated: January 10, 2020
Received: January 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,

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)*
K192967

Device Name
Medacta Shoulder System

Indications for Use *(Describe)*
Medacta Shoulder System – Reverse

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 rotator cuff deficient shoulder joint, severe arthropathy or a previously failed joint replacement and 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 primary stability.

Short Humeral Diaphysis

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.

Medacta Shoulder System - Anatomic

Anatomic Shoulder Prosthesis

The Medacta Anatomic Shoulder Prosthesis 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.

Short Humeral Diaphysis

The Medacta Anatomic Shoulder Prosthesis – Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, 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.

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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2.0 510(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 of Quality and Regulatory, Medacta USA
Date Prepared: October 21, 2019
Date Revised: March 18, 2020

II. Device

Device Proprietary Name:	Medacta Shoulder System
Common or Usual Name:	Shoulder Prosthesis System
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation Number:	21 CFR 888.3660
Product Code (primary):	PHX
Product Code (secondary):	HSD, KWS, KWT
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- Zimmer® Trabecular Metal™ Reverse Shoulder System, Non-Porous Humeral Stems, K122692, Zimmer Incorporated

The following devices are referenced within the submission:

- Medacta Anatomic Shoulder Prosthesis, K170910, Medacta International SA
- Medacta Shoulder System, K170452, Medacta International SA
- Global Unite Anatomic Shoulder, K133834, Depuy

IV. Device Description

The Medacta Shoulder Systems are modular systems intended to be used for shoulder arthroplasty (anatomical or reverse). System components were previously cleared by the FDA under K170910 (anatomic shoulder prosthesis) and K170452 (reverse shoulder prosthesis).

The Long Humeral Diaphysis implants, subject of this 510(k), are implantable devices used to replace the humeral side of the gleno-humeral joint. The product is intended to be used with the Medacta Shoulder System components as an alternative to the Standard Humeral Diaphysis components provided with those systems.

The Medacta Shoulder System Long Humeral Diaphysis couples with the Humeral Reverse Metaphysis (K170452) in the reverse configuration and the cemented and cementless Humeral Anatomic Metaphysis (K170910) in the anatomic configuration. The long humeral diaphysis, provided in 160 mm and 200 mm length options, may be used when additional distal stability in the humeral canal is needed.

The subject devices are manufactured from titanium alloy (Ti6Al7Nb) and are provided sterile in 11 sizes per length option.

V. Indications for Use

Medacta Shoulder System – Reverse

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 rotator cuff deficient shoulder joint, severe arthropathy or a previously failed joint replacement and 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 primary stability.

Short Humeral Diaphysis

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.

Medacta Shoulder System - Anatomic

Anatomic Shoulder Prosthesis

The Medacta Anatomic Shoulder Prosthesis 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.

Short Humeral Diaphysis

The Medacta Anatomic Shoulder Prosthesis – Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, 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.

VI. Comparison of Technological Characteristics

The Medacta Shoulder System Long Humeral Diaphysis and the predicate device share the following characteristics:

- material of construction;
- range of sizes;
- range of lengths;
- fixation; and
- distal shaft shape.

There are no technological differences between the subject and predicate device with respect to the Long Humeral Diaphysis component.

A comparison of key technological features between the subject and predicate device is provided below.

Technological comparison

Parameter	Subject Device	Zimmer® Trabecular Metal™ Reverse Shoulder System, Non-Porous Humeral Stems (K122692)
Material of construction	Titanium alloy	Titanium alloy
Fixation	Cementless Cemented	Cementless Cemented
Distal shaft shape	Circular section, longitudinal grooves	Circular section, longitudinal grooves

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- sterilization validation per UNI EN ISO 11137-1:2015 and AAMI/ANSI/ISO 11137-2:2013;
- fatigue testing per ASTM F1378-17 and
- cadaver studies.

VIII. Conclusion

The information provided within this submission supports that the Medacta Shoulder Systems are as safe and effective as the predicate device; therefore, the Medacta Shoulder Systems are substantially equivalent to the predicate device.