Medacta International SA
% Elizabeth Rose
Manager, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

April 5, 2018

Re: K180089
Trade/Device Name: Medacta Shoulder System Short Humeral Diaphysis
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: March 6, 2018
Received: March 6, 2018

Dear Elizabeth Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180089

Device Name
Medacta Shoulder System Short Humeral Diaphysis

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 rotator cuff deficient 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.

Short Humeral Diaphysis

The Reverse Shoulder Prosthesis- Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with a grossly rotator cuff deficient 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.

Anatomical

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.

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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: January 12, 2018
Date Revised: March 30, 2018

II. Device

Device Proprietary Name:	Medacta Shoulder System Short Humeral Diaphysis
Common or Usual Name:	Shoulder Prosthesis System
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation Number:	21 CFR 888.3660, 21 CFR 888.3670
Primary Product Code:	PHX
Secondary Product Codes:	KWS, MBF
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate devices:

- Medacta Shoulder System, K170452, Medacta International SA

Additional Predicate Devices:

- Aequalis Ascend Flex Shoulder System, K140082, Tornier SAS
- Medacta Anatomic Shoulder Prosthesis, K170910, Medacta International SA

IV. Device Description

The Medacta Shoulder System Short Humeral Diaphysis is an implantable device used to replace the humeral side of the gleno-humeral joint. The product is intended to be used with the Medacta Shoulder System cleared under K170452 and the Medacta Anatomic Shoulder Prosthesis cleared

under K170910, as an alternative to the Standard Humeral Diaphysis - Cementless provided with those systems.

The Medacta Shoulder System Short Humeral Diaphysis couples with the Humeral Reverse Metaphysis (K170452) in the reverse configuration and the Humeral Anatomical Metaphysis – Cementless (K170910) in the anatomic configuration. The short humeral diaphysis implant minimizes the violation of the humeral intramedullary canal (IM).

The product is manufactured from titanium alloy (Ti6Al7Nb) and is provided sterile in 11 sizes.

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 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.

Short Humeral Diaphysis

The Reverse Shoulder Prosthesis- Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with a grossly rotator cuff deficient 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 - Anatomical

Anatomical

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 Short Humeral Diaphysis and the predicate devices share the following characteristics:

- stem size;
- materials of construction;
- coating material; and
- stem shape.

The only technological characteristic difference between the Medacta Shoulder System Short Humeral Diaphysis and the predicate devices is the shorter length of the humeral diaphysis implant. Due to the reduced length of the humeral diaphysis, the length of the coated area was reduced accordingly.

VII. Performance Data

As the subject device is a line extension to previously cleared devices, verification activities, as identified through risk analysis, were conducted on the worst-case implants to written protocols with pre-defined acceptance criteria. Engineering rationales determined that the subject implants did not represent a new worst-case for mechanical testing.

The following performance tests were conducted on the predicate devices and reviewed as part of the Medacta Shoulder System cleared under K170452 and the Medacta Anatomic Shoulder Prosthesis cleared under K170910 submissions:

- coating characterization studies;
- fatigue testing;
- cadaver testing;
- sterilization validation;
- packaging validation;
- shelf life; and
- pyrogenicity.

VIII. Conclusion

Based on the above information, the Medacta Shoulder System Short Humeral Diaphysis can be considered substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, technological characteristics, and performance evaluations. The Medacta Shoulder System Short Humeral Diaphysis is as safe and effective as the predicate devices.