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

December 13, 2017

Re: K171058
Trade/Device Name: Medacta Shoulder System: Threaded Glenoid 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: November 10, 2017
Received: November 13, 2017

Dear Ms. 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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171058

Device Name
Medacta Shoulder System: Threaded Glenoid 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 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 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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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: April 07, 2017
Date Revised: December 11, 2017

II. Device

Device Proprietary Name:	Medacta Shoulder System: Threaded Glenoid 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	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary Predicate:

- Aequalis Reversed Shoulder Prosthesis, K132285, Tornier, SAS
- Encore Reverse Shoulder, K041066, Encore Medical, L.P.

Reference Devices

- Evolis Total Knee System, K081023, Medacta International, SA
- Medacta Shoulder System, K170452, Medacta International, SA

IV. Device Description

The purpose of this submission is to gain clearance for the new Medacta Shoulder System: Threaded Glenoid Baseplate (also referred to as Threaded Glenoid Baseplate) which is part of the Medacta Shoulder System: Reverse; a modular system intended to be used for Reverse Shoulder Arthroplasties (RSA). The Medacta Shoulder System: Threaded Glenoid Baseplate is

an alternative option to the pegged glenoid baseplate that is part of reference device Medacta Shoulder System (K170452). The Medacta Shoulder System: Threaded Glenoid Baseplate is made of titanium alloy.

The Threaded Glenoid Baseplate is intended to replace only the glenoid side of the gleno-humeral joint. The Threaded Glenoid Baseplate is intended to be used in the reverse configuration only. The Threaded Glenoid Baseplate is designed to be fixed on the glenoid bone by means of a central threaded post and the help of Glenoid Polyaxial Locking Screws. The Glenoidsphere is intended to be assembled with a Glenoid Baseplate by means of a taper Morse connection and secured by a central securing screw. The Threaded Glenoid Baseplate directly couples with the Glenoid Polyaxial Locking Screws and Glenoidsphere as part of the Medacta Shoulder System (K170452).

The Medacta Shoulder System is similar to predicate devices Tornier's Aequalis Reversed Shoulder Prosthesis (K132285), Encore's Reverse Shoulder (K041066) and reference device Medacta's Shoulder System (K170452).

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 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 fixation.

VI. Comparison of Technological Characteristics

The Medacta Shoulder System: Threaded Glenoid Baseplate and the predicate devices share the following characteristics:

- Indications for Use
- Materials
- Design
- Sterile
- Coating
- Threaded
- Method of Fixation
- Lengths

The Medacta Shoulder System: Threaded Glenoid Baseplate is technologically different from the predicate devices as follows:

- Diameters

The Medacta Shoulder System: Threaded Glenoid Baseplate is manufactured from Titanium Alloy (Ti6-Al 4-V) according to ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy with a Titanium Y367 coating.

These materials have an extensive amount of biocompatibility history that has been provided in the listed predicate devices' 510(k) submissions; Tornier's Aequalis Reversed Shoulder Prosthesis (K132285), Encore's Reverse Shoulder (K041066) and reference device Medacta's Shoulder System (K170452). The Titanium Y367 coating used on the Medacta Shoulder System: Threaded Glenoid Baseplate is provided by Eurocoating S.p.A. The Titanium Y367 coating was previously reviewed in reference device Medacta's Evolis Total Knee System (K081023).

Additional biocompatibility testing was deemed unnecessary because the materials are the same or similar to the predicate devices and follow standards for manufacturing.

A comparison of the subject and predicate devices are provided in the table below.

Technological comparison

Parameters	**Medacta Shoulder System (Subject Device)**	**Tornier Aequalis Reversed Shoulder Prosthesis K132285 (Predicate Device)**	**Encore Reverse Shoulder K041066 (Predicate Device)**
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Coating	Titanium (ASTM F1580)	Titanium (ASTM F1580)	Hydroxyapatite (ASTM F1185) 3DMatrix Coating
Diameter	Ø24.5 mm and Ø27 mm	Ø25 mm and Ø29 mm	Ø26 mm
Post Length	25 mm, 30 mm and 35 mm	20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm and 50 mm	30 mm
Method of Fixation	Uncemented	Uncemented	Uncemented
Post Design	Threaded	Threaded	Threaded
Device usage	Single Use	Single Use	Single Use
Biocompatibility	Implant with permanent >30 day	Implant with permanent >30 day	Implant with permanent >30 day
Sterilization	Gamma	Gamma	Gamma

Discussion
As seen above, the technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The Medacta Shoulder System: Threaded Glenoid Baseplate is the same or similar to the predicate devices in terms of intended use, materials of construction, design, coating, threaded, method of fixation, lengths and sterility. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the Medacta Shoulder System: Threaded Glenoid Baseplate to the identified predicate devices.

VII. Performance Data

The following mechanical tests are being provided in support of a substantial equivalence determination. Based on the risk analysis, testing was conducted to written protocols with acceptance criteria that were based on standards.

Non-Clinical Studies

- Performance Tests
    - Fatigue Testing: ASTM F1378-12: Standard Specification For Shoulder Prostheses
    - Micromotions Assessment In Reverse Configuration: ASTM F2028-14: Standards Test Methods For Dynamic Evaluation of Glenoid Loosening Or Disassociation Prostheses
- Coating Tests
    - Glenoid Baseplate: Characterization Report Titanium Y367 Coating on Threaded Glenoid Baseplate Medacta
- Pyrogenicity
    - Medacta uses both the Bacterial Endotoxin Test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the Pyrogen Test according to USP chapter <151> for pyrogenicity determination; and
    - Medacta has no intentions of labeling the subject devices as non-pyrogenic or pyrogen free.

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the Medacta Shoulder System: Threaded Glenoid Baseplate is as safe and effective as the predicate devices. Therefore, it is concluded that the Medacta Shoulder System: Threaded Glenoid Baseplate is substantially equivalent to the predicate devices.