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

October 5, 2017

Re: K170452
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, MBF
Dated: September 7, 2017
Received: September 8, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170452

Device Name
Medacta Shoulder System

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 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 for the device to offer full function in vivo.

The glenoid baseplate is intended for cementless application with the addition of screws for primary stability.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

3.0 510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: February 14, 2017
Date Revised: September 07, 2017

II. Device

Device Proprietary Name:	Medacta Shoulder System
Common or Usual Name:	Shoulder Prosthesis, Reverse Configuratin
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Primary Product Code:	PHX
Secondary Product Code:	HSD, MBF
Regulation Number:	21 CFR 888.3660, 21 CFR 888.3690, 21CFR 888.3670
Device Classification	2

III. Predicate Device

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

- Delta Xtend™ Reverse Shoulder System, K062250, DePuy Orthopaedics, Inc.
- Delta Xtend™ Reverse Shoulder Modular Stem, K071379, DePuy Orthopaedics, Inc.

Additional Predicates

- Comprehensive® RS Shoulder System, K072804, Biomet Manufacturing Corporation
- Synthes Epoca Shoulder Prosthesis System, K083439, Synthes (USA)
- Aequalis Shoulder Fracture System & Aequalis Shoulder System, Aequalis Reversed Shoulder Prosthesis, Aequalis Reversed Fracture Shoulder Prosthesis (also referred to as Aequalis Reversed II), K112144, Tornier

Reference Device

- Versafitcup™ Double Mobility Highcross® HXUHMWPE Liners, K092265, Medacta International, SA

IV. Device Description

The purpose of this submission is to gain clearance for the new Medacta Shoulder System. The Medacta Shoulder System is a modular system intended to be used for Reverse Shoulder Arthroplastises (RSA). The Medacta Shoulder System is composed 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
- Glenoidsphere
- Glenoid Polyaxial Locking Screws
- Reverse Metaphysis Screw
- Glenoidsphere Screw

The Humeral Diaphysis and Humeral Reverse Metaphysis 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.

The Glenoid Baseplate is intended to be fixed on the glenoid bone by means of a central press-fit and with the help of Glenoid Polyaxial Locking Screws. The Glenoidsphere is intended to be assembled with the Glenoid Baseplate by means of a taper Morse connection and secured by the Glenoidsphere Screw.

The Glenoidsphere Screw, Reverse Metaphysis Screw, and Glenoid Polyaxial Locking Screws are made of Ti alloy enhanced with Type-II anodization.

The Medacta Shoulder System is similar to the predicate devices DePuy Delta Xtend™ (K062250 and K071379), Biomet Comprehensive® RS Shoulder System (K072804) and Tornier Aequalis Reversed II (K112144).

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 and the predicate devices share the following characteristics:

- indications for use;
- materials;
- design;
- sterile;
- coating;
- thread design; and
- device usage

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

- sizes;
- lengths; and
- diameters

Biocompatibility testing conducted on the predicate devices for the same or similar materials supports the biological safety of the Medacta Shoulder System. The Medacta Shoulder System components are manufactured from the following materials:

- Titanium Alloy (Ti6-Al 4-V) ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy
- Titanium Alloy (Ti6-Al 7-Nb) ISO 5832-11 Second Edition 2014-09-15: Implants For Surgery – Metallic Materials – Part 11: Wrought Titanium 6–Aluminium 7-Niobium Alloy
- Cobalt-Chromium-Molybdenum alloy (Co-Cr-Mo) per ISO 5832-12 Second Edition 2007-05-01: Implants For Surgery-- Metallic Materials -- Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy [Including: Technical Corrigedum 1 (2008)]
- Ultra High Molecular Weight Polyethylene (UHMWPE) Highcross

These materials have an extensive amount of biocompatibility data that has been provided in the listed predicate devices' 510(k) submissions DePuy Delta Xtend™ (K062250 and K071379), Biomet Comprehensive® RS Shoulder System (K072804) and Tornier Aequalis Reversed II (K112144), as well as the UHMWPE Highcross reviewed in reference device Versafitcup™ Double Mobility Highcross® HXUHMWPE Liners (K092265).

The Titanium Y367 + Hydroxyapatite "Osprovit®" coating used on the Medacta Shoulder System - Humeral Diaphysis Cementless component is provided by Eurocoating S.p.A. The Hydroxyapatite "Osprovit®" coating used on the Medacta Shoulder System - Humeral Reverse Metaphysis and Glenoid Baseplate components is provided by Eurocoating S.p.A.

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)**	**DePuy Delta Xtend™ K062250 and K071379 (Predicate Device)**	**Biomet Comprehensive® RS Shoulder System K072804 (Predicate Device)**	**Tornier Aequalis Reversed II K112144 (Predicate Device)**
Material	Titanium Alloy, Cobalt Chromium, UHMWPE	Titanium Alloy, Cobalt Chromium, UHMWPE	Titanium Alloy, Cobalt Chromium, UHMWPE	Titanium Alloy, Cobalt Chromium, UHMWPE
Coating	Titanium (ASTM F1580) Hydroxyapatite (ASTM F1185)	Hydroxyapatite (ASTM F1185)	Titanium (ASTM F1580) Hydroxyapatite (ASTM F1185)	Titanium (ASTM F1580) Hydroxyapatite (ASTM F1185)
Bone Cement	Cemented/ Cementless	Cemented/ Cementless	Cemented/ Cementless	Cemented/ Cementless
System Components	STD Humeral Diapyhsis (Cementless/Cemented), Humeral Reverse Metaphysis, Humeral Reverse HC Liner, Glenoid Baseplate, Glenoid Polyaxial Locking Screw, Glenoidsphere	STD Humeral Diapyhsis (Cementless/Cemented), Humeral Reverse Metaphysis, Humeral Reverse Liner, Glenoid Baseplate, Glenoid Polyaxial Locking Screw, Glenoidsphere	STD Humeral Diapyhsis (Cementless/Cemented), Humeral Reverse Metaphysis, Humeral Reverse Liner, Glenoid Baseplate, Glenoid Polyaxial Locking Screw, Glenoidsphere	STD Humeral Diapyhsis (Cementless/Cemented), Humeral Reverse Metaphysis, Humeral Reverse Liner, Glenoid Baseplate, Glenoid Polyaxial Locking Screw, Glenoidsphere
Device usage	Single Use	Single Use	Single Use	Single Use
Biocompatibility	Implant with permanent >30 day (Equivalency determined)	Implant with permanent >30 day	Implant with permanent >30 day	Implant with permanent >30 day
Sterilization	Gamma and EO	Gamma and EO	Gamma and EO	Gamma and EO

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 is the same or

similar to the predicate devices in terms of intended use, materials of construction, design, coating, thread design, device usage, 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 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 and pre-submission submitted to review testing protocols, testing was conducted to written protocols with acceptance criteria that were based on standards.

Non-Clinical Studies

- Characterization Tests
  - Validation Cadaveric Workshop Evaluations
  - ROM of the Medacta Shoulder System-RSA
  - Humeral Diaphysis Assessment of Design and Dimensions
  - Design Validation Report
- Performance Tests
  - Wear Test: ASTM F1378-12: Standard Specification For Shoulder Prosthesis
  - Fatigue Testing: ASTM F1378-12: Standard Specification For Shoulder Prosthesis
  - Static Fatigue Testing: ASTM F1378-12: Standard Specification For Shoulder Prosthesis
  - Micromotions Assessment In Reverse Configuration: ASTM F2028-14: Standards Test Methods For Dynamic Evaluation of Glenoid Loosening Or Disassociation Prostheses
  - Static Fatigue Testing: ASTM F543-13: Standard Specification And Test Methods For Metallic Medical Bone Screws
- Coating Tests
  - Humeral Reverse Metaphysis: ASTM F2024-10: Standard Practice For X-ray Diffraction Determination Of Phase Content Of Plasma-Sprayed Hydroxyapatite Coatings
  - Glenoid Baseplate: ASTM F2024-10: Standard Practice For X-ray Diffraction Determination Of Phase Content Of Plasma-Sprayed Hydroxyapatite Coatings
  - Humeral Diaphysis: ASTM F2024-10: Standard Practice For X-ray Diffraction Determination Of Phase Content Of Plasma-Sprayed Hydroxyapatite Coatings

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.
- 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 the Medacta Shoulder System is as safe and effective as the predicate devices. Therefore, it is concluded that the Medacta Shoulder System is substantially equivalent to the predicate devices.

----------This space intentionally left blank----------