DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medacta International SA
% Ms. Roshana Ahmed, M.A., RAC
Associate Director, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

August 16, 2017

Re: K170910
Trade/Device Name: Medacta Anatomic Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: July 17, 2017
Received: July 18, 2017

Dear Ms. Ahmed:

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 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170910

Device Name

Medacta Anatomic Shoulder Prosthesis

Indications for Use *(Describe)*

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.

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

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: July 17, 2017

II. Device

Device Proprietary Name:	Medacta Anatomic Shoulder Prosthesis
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:	KWS
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- Synthes Epoca Shoulder Prosthesis System, K083439, Synthes (USA)

Additional Predicates:

- Depuy Global Unite Shoulder System, K101996, Depuy (Ireland)
- Global Advantage Shoulder, Global Advantage Humeral Stem, Global Advantage Eccentric Head, K992065, Depuy Orthopaedics, Inc.
- Aequalis™ Ascend™ Flex Shoulder System, K122698, Tornier SAS
- Aequalis Universal Shoulder Glenoid, K994393, Tornier, S.A.

The following reference devices are cited within the submission:

- Medacta Shoulder System, K170452, Medacta International SA
- Versafitcup™ Double Mobility Highcross® HXUHMWPE Liners, K092265, Medacta International SA
- Aequalis Shoulder Fracture System & Aequalis Shoulder System, K060209, Tornier
- Total Hip Prosthesis System Quadra S + CoCrMo Femoral Ball Head + Apricot, K072857, Medacta International SA

IV. Device Description

The Medacta Anatomic Shoulder Prosthesis is a modular system intended to be used for anatomical shoulder arthroplasty.

The Medacta Anatomic Shoulder Prosthesis is composed of the following components:

- Standard Humeral Diaphysis – Cementless (sizes 6 to 16)
- Standard Humeral Diaphysis – Cemented (sizes 6 to 16)
- Humeral Anatomical Metaphysis – Cementless (128°, 135° and 142° inclinations, sizes 6 to 16)
- Humeral Anatomical Metaphysis – Cemented (128°, 135° and 142° inclinations, sizes 6 to 16)
- Double Eccenter
- Cobalt-Chromium Humeral Head (10 sizes, Ø 40 mm to Ø 58 mm)
- Highcross PE Pegged Glenoid (10 sizes, Ø 40 mm to Ø 58 mm)
- Humeral Stem Screw

The Standard Humeral Diaphysis and the Humeral Anatomical Metaphysis are intended to be assembled together by means of a cylindrical driven-fit coupling and tightened by the Humeral Stem Screw. The Double Eccenter is also connected to the Humeral Anatomical Metaphysis by means of a press-fit cylinder and a securing screw. The Cobalt-Chromium Humeral Head is coupled to a Double Eccenter by means of a taper Morse connection.

The Glenoid Anatomical Implant is composed of the Highcross PE Pegged Glenoid only, which is cemented into the glenoid bone.

The Medacta Anatomic Shoulder Prosthesis components are single-use only, are provided sterile via gamma irradiation or ethylene oxide, and are packaged individually.

The standard humeral diaphysis, humeral anatomical metaphysis, double eccenter, and humeral stem screw are manufactured from titanium alloy. The humeral head is manufactured from CoCr, and the highcross glenoid is manufactured from polyethylene.

V. Indications for Use

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.

VI. Comparison of Technological Characteristics

The Medacta Anatomic Shoulder Prosthesis and the predicate devices share the following characteristics:

- Indications for Use
- Components
- Size
- Materials
- Design
- Coating

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

- Surface treatment of the cementless components

Discussion

As seen above, the technological difference between the subject and predicate device does not raise different questions of safety or effectiveness and performance data submitted within this 510(k) supports this difference.

VII. Performance Data

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

Non-Clinical Studies

- Coating characterization studies
  - Metallographic, SEM, and XRD analyses
- Mechanical Testing
  - Fatigue Testing in accordance with:
    - ASTM F1378-12 *Standard Specification for Shoulder Prosthesis*
    - ISO 7206-4 Third Edition 2010-06-15 *Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 4: Determination of Endurance Properties and Performance of Stemmed Femoral Components* [Including Amendment 1 (2016)]
  - Wear Testing in accordance with:
    - ASTM F1378-12 *Standard Specification for Shoulder Prosthesis*
    - ASTM F2028-14 *Standard Test Methods For Dynamic Evaluation Of Glenoid Loosening Or Disassociation Prostheses*
    - ISO 14242-1:2002 *Implants for surgery - Wear of total hip-joint prostheses - Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*
    - ISO 14242-2:2000 *Implants for surgery – Wear of total hip-joint prostheses – Part 2: Methods of measurement*
    - ISO 17853:2011 *Wear of implants materials -- Polymer and metal wear particles -- Isolation and characterization*
  - Range of Motion Analysis
  - Micromotion Assessment in accordance with:
    - ASTM F2028-14 *Standard Test Methods For Dynamic Evaluation Of Glenoid Loosening Or Disassociation Prostheses*
    - ASTM F1839-08 (Reapproved 2012) *Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments*
    - ASTM F1378-12 *Standard Specification for Shoulder Prosthesis*
  - Axial Disassembly Testing in accordance with
    - ASTM F2009-00 (Reapproved 2011) *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses*
    - ASTM F1378-12 *Standard Specification for Shoulder Prosthesis*
- Cadaver Testing

- Sterilization Validation in accordance with:
  - AAMI/ANSI/ISO 11137-1:2006 (R2015) *Sterilization of Healthcare Products - Radiation - Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*
  - AAMI/ANSI/ISO 11137-2:2013 *Sterilization of Healthcare Products – Radiation - Part 2: Establishing the Sterilization Dose*
  - AAMI/ANSI/ISO 11135:2014 *Sterilization Of Health Care Products – Ethylene Oxide – Requirements For Development, Validation And Routine Control Of A Sterilization Process for Medical Devices*
- Ethylene Oxide Residuals in accordance with:
  - AAMI/ANSI/ISO 10993-7:2008(R)2012 *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*
- Bacterial Endotoxin Testing (LAL Method)
- Packaging validation in accordance with:
  - ISO 11607-1 First Edition 2006-04-15 *Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems* [Including: Amendment 1 (2014)]
  - ISO 11607-2 First Edition 2006-04-15 *Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes* [Including: Amendment 1 (2014)]
- Shelf-life studies in accordance with:
  - ISO 11607-1 First Edition 2006-04-15 *Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems* [Including: Amendment 1 (2014)]
  - ASTM F1980-16 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

VIII. Conclusion

The information provided above supports that the Medacta Anatomic Shoulder Prosthesis is as safe and effective as the predicate devices. Although there is a minor difference in surface treatment between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the Medacta Anatomic Shoulder Prosthesis is substantially equivalent to the predicate devices.