September 20, 2023

Medacta International S.A.
% Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K230011
Trade/Device Name: Mpact Extension
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: August 21, 2023
Received: August 22, 2023

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,

Limin Sun -S

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230011

Device Name
Mpact Extension

Indications for Use *(Describe)*

The Mpact implants are designed for cementless use in total hip arthroplasty in primary or revision surgery. The patient should be skeletally mature.

The patient's condition should be due to one or more of:

• Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriatic arthritis, congenital hip dysplasia, ankylosing spondylitis.
• Avascular necrosis of the femoral head.
• Acute traumatic fracture of the femoral head or neck.
• Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present

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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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, Quality, Regulatory, and Clinical, Medacta USA
Date Prepared: September 20, 2023

II. Device

Device Proprietary Name:	Mpact Extension
Common or Usual Name:	Total Hip Acetabular Components
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Primary Product Code:	LPH
Secondary Product code	LZO
Regulation Number:	21 CFR 888.3358 and 21 CFR 888.3353
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:
Primary predicate device

- Medacta International SA, MPACT, K103721

Additional predicate devices

- Medacta International SA, MPACT Extension, K132879
- Medacta International SA, MPACT Extension, K122641
- Medacta International SA, MPACT Extension, K183582

Reference device:

- Medacta International SA, Versafitcup CC Trio, K103352

IV. Device Description

The Mpact Extension implants are a line extension to Medacta's Mpact (K103721) and Mpact Extensions (K122641, K132879, K183582 and K200391) Systems and are designed to be used with the Medacta Total Hip Prosthesis System. Specifically, the devices subject of this submission are:

- Liners sizes 22/A and 28/A of each design type (flat, hooded, offset +4mm and face changing +10°);
- Acetabular Shells size Ø44 of each design type (No-hole, Two-holes and Multi-holes);
- Acetabular Shells sizes from Ø42T to Ø58T of each design type (No-hole, Two-holes and Multi-holes) allowing to be coupled with an increase size of liner.

The Mpact Extension implants are sterile implantable devices intended to be used during Total Hip Arthroplasty: the acetabular shells together with their respective liners are used to replace the acetabulum.

Analogously to the predicate devices, the subject acetabular shells are made of Ti6Al4V according to ASTM F136-13 and Ti coated according to ASTM F1580-18, while the subject liners are made of High-Cross ultra-high molecular weight polyethylene (UHMWPE).

V. Indications for Use

The Mpact implants are designed for cementless use in total hip arthroplasty in primary or revision surgery. The patient should be skeletally mature.
The patient's condition should be due to one or more of:

- Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriatic arthritis, congenital hip dysplasia, ankylosing spondylitis.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.

VI. Comparison of Technological Characteristics

The Mpact Extension implants are identical to the predicate devices, Mpact System (K103721, K122641, K132879 and K183582), with regards to the following characteristics:

- substrate and coating materials;
- biocompatibility;
- device usage;
- sterility;
- shelf-life; and
- packaging.

The Mpact Extension implants differ from the predicate devices, Mpact System (K103721, K122641, K132879 and K183582), with respect to:

- sizes;
- acetabular shells compatibility with liners;
- liners locking mechanism (n° of tabs); and
- acetabular shells coating thickness.

VII. Performance Data

Based on the risk analysis, performance testing were conducted to written protocols. The following rationales and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Mpact range extension - Acetabular cup fatigue assessment
  - Mpact range extension - Acetabular cup deformation assessment
  - MPACT PE HC liners size A – Stability test report according to ASTM F1820 Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device
  - Mpact new sizes – Evaluation of impingement risk rationale
  - Mpact range extension - Evaluation of ROM according to EN ISO 21535 *Non-active Surgical implants - Joint replacement implants – Specific requirements for hip-joint replacement implants*
  - Mpact PE HC liner sizes Ø22/A and Ø28/A - Rationale for wear test

- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

- *BIOCOMPATIBILITY* assessment

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the subject Mpact Extension devices are substantially equivalent to the predicate devices.