March 21, 2019

Medacta International SA
% Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K183582
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: March 1, 2019
Received: March 4, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.03.21 20:36:00 -04'00'

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)*
K183582

Device Name
MPACT Extension

Indications for Use *(Describe)*
The MPACT Extension 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 Affairs Manager, Medacta International SA

Date Prepared: Dec 20, 2018
Date Revised (1) : Jan 24, 2018
Date Revised (2) : Feb 28, 2019
Date Revised (3) : Mar 15, 2019

II. Device

Device Proprietary Name:	MPACT Extension
Common or Usual Name:	Acetabular Liners
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code:	LPH
Secondary Product Code:	LZO
Regulation Number:	21CFR 888.3358 and 21 CFR 888.3353
Device Classification	II

III. Predicate Device

For the MPACT Extension System, substantial equivalence is claimed to the following primary predicate device:

- MPACT, K103721, Medacta International SA

Moreover, substantial equivalence is claimed to the following reference devices:

- MPACT Extension, K122641, Medacta International SA ;
- MPACT Extension, K132879, Medacta International SA ;
- DePuy Synthes Pinnacle Altrx Acetabular liners (K072963, K102423, and K132959) ; and
- Zimmer Biomet G7 Acetabular System (K121874).

IV. Device Description

The MPACT implants subject of this submission are comprised of the following products:

- 33 sizes of Offset +4mm PE liners; and
- 32 sizes of Face-changing +10° PE liners.

These liners are a component of a total hip joint prosthesis that is used to replace the acetabulum. The component is an inner liner made of High-Cross ultra-high molecular weight polyethylene (UHMWPE); which is inserted in the Acetabular shell.

They are all a line extension to Medacta's MPACT (K103721), and MPACT Extensions (K122641 and K132879) Systems and are designed to be used with the Medacta Total Hip Prosthesis System. In detail, the Liners subject of the current submission are compatible with the MPACT No-Hole and Two-Hole (K132879), MPACT Multi-Hole and Rim-Hole (K132879); and the Mpact 3D Metal Acetabular Shells (K171966).

As regards to the femoral head components, the MPACT Extension Liners can be combined with the CoCr Ball Heads (K072857 and K080885), MectaCer Biolox Option Heads (K131518), or with the MectaCer BIOLOX® Forte (K073337) or MectaCer BIOLOX® Delta Femoral Heads (K112115).

V. Indications for Use

The MPACT Extension 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 Offset 4mm PE HC Liners and Face-changing 10° PE HC Liners and the reference devices DePuy Synthes Pinnacle Altrx Acetabular liners (K072963, K102423, and K132959) and the Zimmer Biomet G7 Acetabular System (K121874), share the following characteristics:

- sizes
- design
- device usage;

Moreover, with the primary Medacta predicate device MPACT Liners cleared under K103721, and with the additional Medacta reference devices MPACT Extension (K122641 and K132879) they also share the following characteristics:

- material of construction;
- design/ locking mechanism
- biocompatibility;
- sterility;
- shelf life; and
- packaging.

The fundamental scientific technology of the subject devices is substantially equivalent to the predicate devices. The safety and effectiveness of the subject devices is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- Performance Tests
    - Static/Dynamic Compressive Load Testing: *ASTM F1820-13: Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device*
    - Static Lever-out Testing: *ASTM F1820-13: Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device*
    - Range of Motion*: EN ISO 21535 (2007): Non-active surgical implants – Joint replacement implants – Specific requirements for hip-joint replacement implants.*

- Pyrogenicity (valid for all the subject devices)
    - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination; and
    - the subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the MPACT Extension implants are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The MPACT Extension implants are as safe and effective as the predicate devices, MPACT and MPACT extension (K103721, K122641, and K132879), DePuy Synthes Pinnacle Altrx Acetabular liners (K072963, K102423, and K132959), Zimmer Biomet G7 Acetabular System (K121874).