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

March 27, 2018

Re: K171966
Trade/Device Name: Mpact® 3D Metal™ Implants and Augments 3D Metal™
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: February 19, 2018
Received: February 20, 2018

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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171966

Device Name
Mpact® 3D Metal™ Implants and Augments 3D Metal™

Indications for Use *(Describe)*

Mpact 3D Metal Implants

The Mpact 3D Metal Implants is designed to be used in total hip arthroplasty, for primary or revision surgery.
The patient should be skeletally mature.
Total hip arthroplasty is indicated in the following cases:

• Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic 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.

Augments 3D Metal

The Augments 3D Metal are intended to be used in combination with the Mpact 3D Metal Multi-hole acetabular cup in hip replacement surgeries.

The Augments 3D Metal are indicated in cases of:

• Congenital dysplasia
• Acetabular fractures
• Revision of previous implants in presence of insufficient bone quality or seriously altered bone structures.

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.

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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Date Prepared: March 27, 2018

II. Device

Device Proprietary Name:	Mpact® 3D Metal™ Implants and Augments 3D Metal™
Common or Usual Name:	Total Hip Prosthesis
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Primary Product Code:	LPH, LZO
Regulation Number:	21 CFR 888.3358
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Mpact® Acetabular System, K103721, Medacta International SA
- Mpact® Extension (also referred to as Mpact Acetabular System), K122641, Medacta International SA
- Mpact® Extension (also referred to as Mpact Acetabular System), K132879, Medacta International SA
- DePuy Universal Gription™ TF Cones (Knee) & DePuy Gription™ TF Acetabular Augment System (Hip) (also referred to as DePuy Gription™ Augments), K100391, DePuy Orthopaedics, Inc.

The following reference device are cited within the submission:

- 3DMetal Tibial Cones, K170149, Medacta International SA
- Delta TT Acetabular System, K112898, Limacorporate S.p.A.
- Delta TT Acetabular System, K141395, Limacorporate S.p.A.

IV. Device Description

The Mpact® 3D Metal™ Implants and Augments 3D Metal™ are a line extension to the Mpact Acetabular System (K103721) which offers different acetabular shells, liner options, a screw plug, and cancellous bone screws for primary to complex hip revision solutions. The subject devices are manufactured using an Electron Beam Melting (EBM) process with titanium alloy powder. The devices subject to this 510(k) consist of two-hole shells, multi-hole shells, and augments.

The Mpact® 3D Metal™ Acetabular Two-Hole Shells are hemispherical porous shells with multiple liner options and two screw holes to be used with previously 510(k) cleared cancellous bone screws for additional fixation.

The Mpact® 3D Metal™ Acetabular Multi-Hole Shells are hemispherical porous shells with multiple liner options with up to 17 screw holes to be used with previously 510(k) cleared cancellous bone screws for additional fixation. The Mpact® 3D Metal™ Acetabular Shells can be coupled with standard Highcross Ultra-High Molecular Weight Polyethylene (UHMWPE) liners.

The Augments 3D Metal™ are porous metal augments designed to act as a defect filling implant in cases of severe bone loss in the acetabulum to help increase the stability of the acetabular component. The Augments 3D Metal™ are intended to be used in conjunction with the Mpact® Multi-Hole Acetabular Shells and Mpact® 3D Metal™ Multi-Hole Acetabular Shells to aid with bone defects in complex acetabular surgeries and provide surgeons with a prosthetic alternative to structural allograft in cases of segmental deficiencies.

V. Indications for Use

Mpact 3D Metal Implants
The Mpact 3D Metal Implants is designed to be used in total hip arthroplasty, for primary or revision surgery.
The patient should be skeletally mature.
Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint: as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis or psoriactic 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.

Augments 3D Metal
The Augments 3D Metal are intended to be used in combination with the Mpact 3D Metal Multi-hole acetabular cup in hip replacement surgeries.

Augments 3D Metal are indicated in cases of:

- Congenital dysplasia
- Acetabular fractures
- Revision of previous implants in presence of insufficient bone quality or seriously altered bone structures.

VI. Comparison of Technological Characteristics

The Mpact® 3D Metal™ Implants and Augments 3D Metal™ and the predicate devices share the following characteristics:

- diameter (for the Acetabular Shells);
- sizes;
- thickness;
- substrate materials;
- fixation;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Mpact® 3D Metal™ Implants and Augments 3D Metal™ are technologically different from the predicate devices only by the manufacturing process. The subject devices are manufactured using the EBM process whereas the previously 510(k) cleared Mpact Acetabular System was manufactured using a turning process.

The Mpact® 3D Metal™ Implants and Augments 3D Metal™ are manufactured with a titanium alloy (Ti6Al4V) according to ASTM F136-13 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and ISO 5832-3:1996 Implants for Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy). The components are manufactured using the EBM (Electron Beam Melting) process which is identical to Medacta's 3DMetal Tibial Cones (K170149).

These materials have a long history of use in implantable orthopedic devices and material information has been provided in previous Medacta's 510(k) submissions for the Mpact Acetabular Systems (K103721, K122641, and K132879).

Due to the extensive history of use in currently marketed medical devices, as well as similarities in the manufacturing processes between the subject and reference devices (K170149), additional biocompatibility testing was deemed unnecessary for the Mpact® 3D Metal™ Implants and Augments 3D Metal™.

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
  - coating characterization and testing:
    - ASTM F1854-15 Standard Test Method For Stereological Evaluation Of Porous Coatings On Medical Implants;
    - fatigue shear testing: ASTM F1160-14 Standard Test Method For Shear And Bending Fatigue Testing Of Calcium Phosphate And Metallic Medical And Composite Calcium Phosphate/Metallic Coatings;
    - static shear testing: ASTM F1044-05 (Reapproved 2011) Standard Test Method For Shear Testing Of Calcium Phosphate Coatings And Metallic Coatings;
    - tensile strength testing: ASTM F1147-05 (Reapproved 2011) Standard Test Method For Tension Testing Of Calcium Phosphate And Metal Coatings;
  - deformation testing: ISO 7206-2:1996 Implants For Surgery - Partial And Total Hip Joint Prostheses – Part 2: Articulating Surfaces Made Of Metallic, Ceramic And Plastics Materials;
  - locking mechanism strength (push-out, lever-out, and torque-out): ASTM F1820 - 13 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
  - range of motion testing: EN ISO 21535:2009 Non-Active Surgical Implants - Joint Replacement Implants - Specific Requirements for Hip-Joint Replacement Implants (ISO 21535:2007/Amendment 1:2016);
  - dynamic compression testing of acetabular shell and augment assembly; and
  - fatigue testing of the acetabular shell.

- Pyrogenicity
  - 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.

VIII. Conclusion

Based on the above information, the Mpact® 3D Metal™ Implants and Augments 3D Metal™ can be considered 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® 3D Metal™ Implants and Augments 3D Metal™ are as safe and effective as the predicate devices, Mpact Acetabular Systems (K103721, K122641 and K132879) and DePuy Gription™ Augments (K100391).