December 20, 2021

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

Re: K202568
Trade/Device Name: Mpact® 3D Metal Implants - DMLS Technology
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: November 22, 2021
Received: November 23, 2021

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,

for

Limin Sun, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202568

Device Name
Mpact® 3D Metal Implants - DMLS Technology

Indications for Use *(Describe)*

The Mpact® 3D Metal™ 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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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
clussier@medacta.us.com
Date Prepared: September 1, 2020
Date Revised: December 20, 2021

II. Device

Device Proprietary Name:	Mpact® 3D Metal Implants - DMLS Technology
Common or Usual Name:	Total Hip Prosthesis
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

Considering the Mpact® 3D Metal Implants manufactured through DMLS Technology, substantial equivalence is claimed to the following device:

- Mpact® 3D Metal Acetabular Shells and 3D Metal Augments, K171966, Medacta International SA

Moreover, considering the Compression Polyaxial Locking Screws, substantial equivalence is claimed to the following devices:

- Medacta International SA, Mpact Acetabular System, Cancellous Bone Screws flat head, K103721, Medacta International SA
- Medacta International SA, Mpact Extension, Cancellous Bone Screws flat head, K132879, Medacta International SA

In addition, the following reference device is cited within the submission:

- Medacta International SA, Medacta Shoulder System, Glenoid Polyaxial Locking Screws (K170452)

IV. Device Description

The Mpact® 3D Metal Implants - DMLS Technology are sterile implantable devices intended to be used during Total Hip Arthroplasty. The devices subject of this submission are:

- Mpact® 3D Metal Acetabular Shells Two-Hole - Ø 46-66 mm - manufactured through DMLS Technology;
- Mpact® 3D Metal Acetabular Shells Multi-Hole - Ø 46-72 mm - manufactured through DMLS Technology;
- Mpact® 3D Metal Acetabular Shells Multi-Hole Thin - Ø 48-60 mm - manufactured through DMLS Technology; and
- Compression Polyaxial Locking Screws - 11 sizes depending on screw length: from 20 to 70mm in 5mm steps.

The Mpact® 3D Metal Acetabular Shells manufactured through DMLS Technology are a line extension to the Mpact® 3D Metal Acetabular Shells and 3D Metal Augments (K171966) and to the Mpact® Acetabular Systems Shells (K103721, K122641 and K132879) and are designed to be used with the Medacta Total Hip Prosthesis System.
The subject Mpact® 3D Metal Acetabular Shells are manufactured using a Direct Metal Laser Sintering (DMLS) process with titanium alloy powder. DMLS is a metal additive layer manufacturing process that uses a precise and high-wattage laser to "sinter" powdered metals and alloys to form accurate, complex and fully-functional metal parts directly from CAD data.

Compression Polyaxial Locking Screws have been designed to provide fixation of implants to the cancellous bone and they can be considered a line extension to the predicate devices, Cancellous Bone Screws flat head, previously cleared within K103721 and K132879. The subject screws have a thread diameter of 6.5 mm and they can be coupled with implants that have dedicated fixation holes with a spherical seat shape of Ø8mm.
The outer screw of the Compression Polyaxial Locking Screws is made of titanium alloy (Ti6-Al4-V) according to ISO 5832-3:2016, Implants for Surgery – Metallic materials – Part 3: Wrought titanium 6-aluminum 4-vanadium alloy, while, the inner part, not in contact with bone, is made of Co-Cr-Mo alloy according to ISO 5832-12:2019, Implants for Surgery – Metallic materials – Part 3: Wrought cobalt-chromium-molybdenum alloy.

V. Indications for Use

The Mpact® 3D Metal 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

- *Mpact® 3D Metal Acetabular Shells - DMLS Technology*

The Mpact® 3D Metal Acetabular Shells manufactured through DMLS Technology and the predicate devices (K171966) share the following characteristics:

- indication for use;
- shape and design;
- diameters;
- materials;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The only difference between the Mpact® 3D Metal Acetabular Shells manufactured through DMLS Technology and the predicate devices (K171966) is the manufacturing process.

- *Compression Polyaxial Locking Screws*

The subject Compression Polyaxial Locking Screws and the predicate cancellous bone screws flat head (K103721 and K132879) share the following characteristics:

- sizes;
- thread outer diameter
- head shape
- outer material;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The subject Compression Polyaxial Locking Screws differ from the predicate cancellous bone screws flat head (K103721 and K132879) with respect to:

- neck diameter; and
- head height.
- thread core diameter;
- head diameter;
- recess; and
- inner material.

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Mpact 3D Metal Two-Hole, Validation Workshop
  - Mpact 3D Metal Multi-Hole + Augment, Cadaver workshop and Evaluation forms
  - Validation rational Mpact 3D Metal Multi-Hole Thin
  - Compression Polyaxial Locking Screw Design Validation Report (Cadaver Workshop), according to M07.85.003 rev.3. *Test Report A1.*

- *PERFORMANCE TESTING*
  - 3D Metal DMLS Stereological Evaluation according to *ASTM F1854-15 Standard Test Method For Stereological Evaluation Of Porous Coatings On Medical Implants* and EndoLab Test Report No. 167.180116.10.2760 Rev. 1
  - 3D Metal DMLS - Static and Fatigue Shear Test according to *ASTM F1044-05 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings*, *ASTM F1160-14 Standard Test Method For Shear And Bending Fatigue Testing Of Calcium Phosphate And Metallic Medical And Composite Calcium Phosphate/Metallic Coatings*, Medacta Test Protocol IL 07.09.476 Rev.0 and EndoLab Test Reports 167.180404.70.1049 Rev. 0 and 167.180406.70.1050 Rev. 0
  - 3D Metal DMLS - Tension Test according to *ASTM F1147-05 Standard Test Method For Tension Testing Of Calcium Phosphate And Metal Coatings*, Medacta Test Protocol IL 07.09.477 Rev. 0 and EndoLab Test Report No. 167.180404.70.1048 Rev. 0
  - Mpact 3D Metal Two-Hole, Multi-Hole and Multi-Hole Thin - Evaluation of ROM according to *EN ISO 21535 Non-active Surgical implants – Joint replacement implants – Specific requirements for hip-joint replacement implants*
  - Mpact 3D Metal - Fatigue and Deformation Test according to Medacta FEM Fatigue and deformation test worst case Rev. 2, Test Protocols IL 07.09.516 Rev. 01 and IL 07.09.342 Rev. 02, Element Test Report No. 00812-008387-1A and Medacta Test Reports
  - Mpact 3D Metal Shell with Liner – Stability test according to *ASTM F1820-13 Standard Test Method For Determining the Forces for Disassembly of Modular Acetabular Devices*, Medacta Test Protocol IL 07.09.596 Rev. 00 and EndoLab Test Reports 167.300310.10.3195 Rev. 0, 167.300310.10.3196-part 1 and part 2 Rev. 0
  - Compression Polyaxial Locking Screw Mechanical Test according to Medacta Protocol IL 07.09.450_rev.0 and Endolab Test report No. 167.171121.120.714 – part 1, 2 and 3. *Test report A2*

- *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*
  - Biocompatibility assessment as per *ISO 10993* series and FDA Biocompatibility Guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the Mpact® 3D Metal Implants - DMLS Technology and the Compression Polyaxial Locking Screws 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® 3D Metal Implants - DMLS Technology and the Compression Polyaxial Locking Screws are as safe and effective as the predicate devices.