January 28, 2026

Medacta International S.A.
% Christopher Lussier
Senior Director, Quality and Regulatory
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K251043
Trade/Device Name: Mpact 3D Metal Implants Extension - 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: December 29, 2025
Received: December 29, 2025

Dear Christopher 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251043

Please provide the device trade name(s).

Mpact 3D Metal Implants Extension – DMLS Technology

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. Submitter

Medacta International SA
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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: April 03, 2025
Date Revised: January 28, 2026

II. Device

Device Proprietary Name:	Mpact 3D Metal Implants Extension – 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, 21 CFR 888.3353
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Mpact 3D Metal Implants – DMLS Technology, K202568, Medacta International SA

Additional Predicate devices:

- Mpact Extension, K230011, Medacta International SA
- Versafitcup CC Trio, K103352, Medacta International SA

IV. Device Description

The Mpact 3D Metal Implants Extension - DMLS Technology are a line extension to the Mpact 3D Metal Acetabular Shells and 3D Metal Augments (K171966, K202568) and to the Mpact Acetabular Systems Shells (K103721, K122641, K132879 and K230011) and are designed to be used with the Medacta Total Hip Prosthesis System. Specifically, the devices subject of this submission are:

- Acetabular shell size Ø44 Two-holes;
- Acetabular shell size Ø44 Multi-holes thin;

- Acetabular shells sizes from Ø42T to Ø58T of both Two-holes and Multi-holes Thin designs, allowing to be coupled with an increase size of liner.

The subject implants are intended to be used during Total Hip Arthroplasty to replace the acetabulum and they are provided individually packed, sterile and single-use. Similarly to the predicate devices, the subject acetabular shells are manufactured using a Direct Metal Laser Sintering (DMLS) process with titanium alloy powder according to ASTM F2924-14.

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

The subject and predicate devices (K202568) are similar with respect to the following characteristics:

- Design;
- Fixation;
- Material;
- Biocompatibility;
- Device usage;
- Packaging;
- Sterilization; and
- Shelf-life.

The subject devices differ from the predicate devices (K202568) with respect to:

- Range of product sizes;
- Liners' compatibility;
- Manufacturing process; and
- Pyramidal net height.

Discussion

The subject devices have been designed to increase the sizes of liners they can be combined with, in order to optimize the head/shell ratio and potentially decrease the risk of head dislocation, due to a higher jumping distance. This difference does not raise any new issue of safety and effectiveness since it is shared with the additional predicate devices (K230011).
No new issue with respect to safety and effectiveness arise due to the partially different manufacturing process since the chemicals/agents are identical and the mechanical performance was found to be acceptable as demonstrated by mechanical testing.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices with respect to the predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Mpact 3D Metal Range extension Fatigue test according to ASTM F3090-24 *Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement*
  - Mpact 3D Metal range extension - Rationale for Stability test
  - Mpact 3D Metal range extension – Evaluation of ROM according to EN ISO 21535 *Non-active Surgical implants - Joint replacement implants – Specific requirements for hip-joint replacement implants*
  - Stereological evaluation according to ASTM F1854-15 *Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants*
  - Static tension test according to ASTM F1147-05 *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings*
  - Static shear test according to ASTM F1044-05 *Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings*
  - Fatigue shear test according to ASTM F1160-14 *Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coating*
  - Taber abrasion test according to ASTM F1978-22 *Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser*
  - Mpact 3D Metal range extension Impingement test according to ASTM F2582-20 *Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components*
  - Mpact 3D Metal range extension Deformation test according to ISO 7206-12 *Partial and total hip joint prostheses — Part 12: Deformation test method for press-fit acetabular components*

- *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 according to ISO 11607-1 *Second Edition 2019-02: Packaging For Terminally Sterilized Medical Devices– Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems* and ISO 11607-2 *Second Edition 2019-02: Packaging For Terminally*

Sterilized Medical Devices- Part 2: Validation Requirements For Forming, Sealing And Assembly Processes

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

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