August 28, 2026

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

Re: K253630
Trade/Device Name: Mpact 3D Metal Foam
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
Dated: July 30, 2026
Received: July 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

For: 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)*
K253630

Device Name
Mpact 3D Metal Foam

Indications for Use *(Describe)*

Mpact 3D Metal Foam is intended to be used in cementless hip replacement surgeries in combination with Medacta F-Cage and a Medacta cemented cup (Apricot or Versacem), or in combination with a Medacta cemented cup only. Mpact 3D Metal Foam, Medacta F-Cage and Apricot are indicated for use in the case of acetabular bony defect during total hip arthroplasty.

Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head when total hip arthroplasty has been chosen.
- Acute traumatic fracture of the femoral head or neck when total hip arthroplasty has been chosen.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement, or total hip arthroplasty.

When the Mpact 3D Metal Foam is used with the Versacem, is also recommended when dislocation prevention is the main driver for the prosthesis choice and the acetabular bone quality is damaged, as in the following cases:

- Elderly patients or poor bone quality.
- Revision for recurrent dislocation in elderly patients with poor bone quality.
- Patients treated with radiotherapy or chemotherapy.

Versacem is intended for cemented use only.

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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510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: November 19, 2025
Date Revised: August 27, 2026

II. Device

Device Proprietary Name:	Mpact 3D Metal Foam
Common or Usual Name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Classification Name:	Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Primary Product Code	LPH
Regulation Number:	21 CFR 888.3358
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Trabecular metal acetabular revision shells, K050937, Zimmer Trabecular

Additional Predicate devices:

- Trabecular metal acetabular revision system cage, K061226, Zimmer Trabecular
- Trabecular metal revision shell liners, K051516, Zimmer Trabecular
- REDAPT Porous Acetabular Shell and Cemented Liner, K150790, SMITH & NEPHEW, INC.
- Mpact Extension, K230011, Medacta International SA
- Mpact acetabular system, K103721, Medacta International SA
- Mpact extension, K122641, Medacta International SA

Reference devices:

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

- GMK 3D Metal Tibial Tray, K221850, Medacta International SA
- M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System, K171595, Medacta International SA
- Medacta Anatomic Shoulder Prosthesis K170910, Medacta International SA

IV. Device Description

The Mpact 3D Metal Foam is an extension of Medacta Mpact 3D Metal acetabular system portfolio intended to be used in hip replacement surgeries. The Mpact 3D Metal Foam includes implantable devices, provided individually packed, sterile and single-use. Specifically, the devices subject of this submission are:

- Mpact 3D Metal Foam Cup, available in 18 sizes, from ø46 mm to ø80 mm (in 2 mm increments) and made of Ti-6Al-4V according to ASTM F2924 by using additive manufacturing.
- Apricot Cup, an High Cross UHMWPE cemented cup available from size 36 mm to size 64 mm (in 2 mm increments) with internal diameters varying with sizes.
- F-Cage, a reinforcement cage made of Titanium Grade 1 according to ASTM F67 and available in 2 versions (Long and Short) and 10 sizes, 5 left and 5 right, from ø46 mm to ø66 mm.

V. Indications for Use

Mpact 3D Metal Foam is intended to be used in cementless hip replacement surgeries in combination with Medacta F-Cage and a Medacta cemented cup (Apricot or Versacem), or in combination with a Medacta cemented cup only. Mpact 3D Metal Foam, Medacta F-Cage and Apricot are indicated for use in the case of acetabular bony defect during total hip arthroplasty.
Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head when total hip arthroplasty has been chosen.
- Acute traumatic fracture of the femoral head or neck when total hip arthroplasty has been chosen.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement, or total hip arthroplasty.

When the Mpact 3D Metal Foam is used with the Versacem, is also recommended when dislocation prevention is the main driver for the prosthesis choice and the acetabular bone quality is damaged, as in the following cases:

- Elderly patients or poor bone quality.
- Revision for recurrent dislocation in elderly patients with poor bone quality.
- Patients treated with radiotherapy or chemotherapy.

Versacem is intended for cemented use only.

VI. Comparison of Technological Characteristics

The subject and predicate devices (K050937, K051516, K061226) are substantially equivalent with respect to the following characteristics:

- Design, except for the Mpact 3D Metal Foam Cup;
- Fixation;
- Materials, except for the Mpact 3D Metal Foam Cup;
- Biocompatibility;
- Device usage; and

- Packaging.

The subject devices differ from the predicate devices (K050937, K051516, K061226) with respect to:

- Range of product;
- Mpact 3D Metal Foam Cup design; and
- Mpact 3D Metal Foam Cup materials.

Discussion

The subject Mpact 3D Metal Foam Cup and Apricot Cup range of sizes, slightly different respect to the one of the predicate devices (K050937, K051516), has been designed to cover a wider population, but it has no impact on safety and effectiveness as demonstrated by fatigue testing.

The different diameters of the subject F-Cage and predicate devices (K061226) do not arise any new issue of safety and effectiveness since both devices cover the same range of product being compatible with the same group of acetabular shells.

The different Mpact 3D Metal Foam Cup design and feature for impactor/alignment with respect to the predicate devices (K050937) do not arise any new issue with respect to safety and effectiveness since it is shared with the reference devices (K202568).

The different material of the subject Mpact 3D Metal Foam Cup and the predicate devices (K050937) does not introduce new questions of safety and effectiveness since the subject devices' material and manufacturing process are shared with the reference devices (K221850, K202568).

Finally, subject devices shelf-life and sterilization is shared with Medacta already cleared devices.

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

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Mpact 3D Metal Foam and Medacta F-Cage, Design validation

- *PERFORMANCE TESTING*
  - Mpact 3D Metal Foam Acetabular Cup Fatigue Test according to ASTM F3090
  - Static tension test according to ASTM F1147
  - Static shear test according to ASTM F1044
  - Dynamic shear according ASTM F1160-14
  - Taber abrasion test according to ASTM F1978
  - Acetabular Cage Fatigue Test – F-Cage
  - Apricot Full PE HC Cemented Cup - ROM Evaluation according to ISO 21535
  - Apricot Full PE HC – Evaluation of impingement risk – Rationale

- *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 devices are substantially equivalent to the predicate devices.