April 23, 2025

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

Re: K242232
Trade/Device Name: Mpact 3D Metal Augments II
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: July 31, 2024
Received: March 19, 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

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)*
K242232

Device Name
Mpact 3D Metal Augments II

Indications for Use *(Describe)*
Mpact 3D Metal Augments are intended for cementless use to the bone interface and are affixed to a compatible Medacta Acetabular shell using bone cement in hip replacement surgeries.
Mpact 3D Metal Augments are indicated in cases of:
• Acetabular dysplasia;
• Acetabular fractures;
• Revision of previous implants in the 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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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: July 31, 2024
Date Revised: April 22, 2025

II. Device

Device Proprietary Name:	Mpact 3D Metal Augments II
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
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:

- Augments 3D Metal™, K171966, Medacta International S.A.

Reference predicate devices:

- 3DMetal Tibial Cones, K170149, Medacta International S.A.
- GMK 3D Metal Tibial Tray, K221850, Medacta International S.A.
- Locking Screw, K170690, Medacta International S.A.
- Humeral stem screw, K170910, Medacta International S.A.
- Double eccenter / Reverse metaphysis screw, K170452, Medacta International S.A.

IV. Device Description

The purpose of this submission is to gain clearance for the Mpact 3D Metal Augments II.

The Mpact 3D Metal Augment II is an acetabular implant intended to be used in Total Hip Arthroplasty cemented to its Medacta compatible Acetabular Shell. It is provided sterile and individually packaged to the end user.

The devices subject of this submission are:

- Mpact 3D Metal Augments II from size Ø46 to Ø80, made of Ti6Al4V according to ASTM F2924;
- Double Augment Technique Screw, made of Ti6Al4V according to ISO 5832-3.

The Mpact 3D Metal Augments II represent the second generation of the Mpact 3D Metal Augments cleared within K171966.

V. Indications for Use

Mpact 3D Metal Augments are intended for cementless use to the bone interface and are affixed to a compatible Medacta Acetabular shell using bone cement in hip replacement surgeries.
Mpact 3D Metal Augments are indicated in cases of:

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

VI. Comparison of Technological Characteristics

The subject Mpact 3D Metal Augments II and the predicate device Mpact 3D Metal Augments (K171966) share the following characteristics:

- cementation;
- material;
- manufacturing process;
- surface finishing;
- three-dimensional porous net structure;
- packaging;
- shelf-life;
- sterilization.

The subject Mpact 3D Metal Augments II and the predicate device Mpact 3D Metal Augments (K171966) differ with respect to the following characteristics:

- range of sizes;
- device design;

- Double Augment Technique Screw.

The subject device can be used as a single augment, identically to the predicate device (K171966) or in a double augment technique in which two augments are attached together with the double augment technique screws.

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

- Design Validation on Mpact 3D metal Augments II

PERFORMANCE TESTING

- Fatigue testing in single and double augment configurations
- Rationale of comparison – EBM Additive Manufacturing Technology

PYROGENICITY

Medacta International does not intend to label the subject devices as non-pyrogenic or pyrogen free.
Control of pyrogenicity is validated through the following primary test methods on all identified representative devices as part of their initial validation prior to submission:

1. Quantification of bacterial endotoxin units (EU) on the device surface after final cleaning and sterilization using the bacterial endotoxin test (LAL test) on the basis of a measured colour-producing reaction proportional to the interaction of Limulus amebocyte lysate (LAL) and endotoxin according to ISO11737-3 and European Pharmacopoeia §2.6.14 (which is harmonized with USP chapter <85> and USP <161>)
2. In-vivo evaluation of pyrogenicity in rabbit, per USP <151>, in conjunction with biocompatibility studies.

BIOCOMPATIBILITY assessment

SHELF-LIFE evaluation

VIII. Conclusion

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