July 31, 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: K241461
Trade/Device Name: Mpact Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip Joint Metal/Polymer Constrained Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: July 29, 2025
Received: July 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241461

Device Name

Mpact Constrained Liner

Indications for Use *(Describe)*

Mpact Constrained Liner is intended to be used as part of a Total Hip Arthroplasty, uncemented in combination with the Mpact and Mpact 3D Metal System acetabular shells.
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
• Acute traumatic fracture of the femoral head or neck
• Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty.

Mpact Constrained Liner is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. Mpact Constrained Liner should be considered only for patients with limited functional demand, as it offers a smaller range of motion than the standard total hip replacement components.

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: May 23, 2024
Date Revised: July 31, 2025

II. Device

Device Proprietary Name:	Mpact Constrained Liner
Common or Usual Name:	Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/polymer
Classification Name:	Hip joint metal/polymer constrained cemented or uncemented prosthesis.
Primary Product Code	KWZ
Regulation Number:	21 CFR 888.3310
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Trident® Constrained Acetabular Insert, K061654, Howmedica Osteonics Corp.

Additional Predicate devices:

- Smith & Nephew, Inc. R3™ Constrained Liner, K111635, Smith & Nephew, Inc.
- Medacta Bipolar Heads, K091967, Medacta International SA
- Mpact® Acetabular System, K103721, Medacta International SA
- Versafitcup™ Double Mobility Highcross, K092265, Medacta International SA

Reference devices:

- Mpact DM Liner Converter, K131458, Medacta International SA
- Cancellous Bone Screws, K200391, Medacta International SA
- Mpact DM Converter, K131458, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the Mpact Constrained Liner.
The Mpact Constrained Liner is an acetabular preassembled liner consisting of an UHMWPE liner incorporating a bipolar head.

The subject device is available in six sizes and two configurations, flat or 10° face-changing.

The Mpact Constrained Liner implants are provided sterile and individually packaged.

V. Indications for Use

Mpact Constrained Liner is intended to be used as part of a Total Hip Arthroplasty, uncemented in combination with the Mpact and Mpact 3D Metal System acetabular shells.
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
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty.

Mpact Constrained Liner is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. Mpact Constrained Liner should be considered only for patients with limited functional demand, as it offers a smaller range of motion than the standard total hip replacement components.

VI. Comparison of Technological Characteristics

The subject Mpact Constrained Liner and the predicate devices (Trident® Constrained Acetabular Insert K061654; Smith & Nephew, Inc. R3™ Constrained Liner K111635) are substantially equivalent with respect to the following characteristics:

- General design;
- Design of the bipolar head;
- Range of sizes;
- Range of motion;
- Locking mechanism;
- Materials;
- Biocompatibility;

- Device usage;
- Packaging and
- Sterilization method.

The subject Mpact Constrained Liner and the predicate devices (Trident® Constrained Acetabular Insert K061654, Smith & Nephew, Inc. R3™ Constrained Liner K111635) differ with respect to the following characteristics:

- Thickness measures;
- Shelf-life.

Discussion

The slight difference in the thickness measures between subject and predicate devices does not pose any risk in terms of safety and performance characteristics, as they are larger with respect to the ones of the predicate devices.
The subject device shelf-life does not affect in any way its safety and performance, as it is shared with the predicate devices Mpact Flat PE Liner, Mpact DM Liner Converter, Medacta Bipolar Head, Cancellous Bone Screws (K103721, K131458, K091967, K200391) and in general with the majority of Medacta devices cleared in US. The predicate devices Mpact Flat PE Liner, Mpact DM Liner Converter, Medacta Bipolar Head, Cancellous Bone Screws (K103721, K131458, K091967, K200391) are substantially equivalent to the subject device in terms of manufacturing materials and main steps of the production process.

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.

Nonclinical Studies

PERFORMANCE TESTING

- Evaluation of Range of Motion, standard reference EN ISO 21535*: Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants*
- Evaluation of the thickness of the components
- Impingement and post-impingement lever-out test, standard references ASTM F2582-20: *Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components* and ASTM F1820-22: *Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices*
- Evaluation of the wear, standard references ISO 14242-1 *Implants for surgery - Wear of total hip-joint prostheses - Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test* and ASTM F732 *Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses*
- Push out test rationale, standard reference ASTM F1820: *Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device*
- Torsion test rationale, standard reference ASTM F1820: *Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device*
- Pull-out and lever-out test, standard reference ASTM F1820-22: *Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices*

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 device is substantially equivalent to the predicate devices.