September 19, 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: K250450
Trade/Device Name: Coated hip implants
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH
Dated: February 18, 2025
Received: September 4, 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250450

Device Name
Coated Hip Implants

Indications for Use *(Describe)*

• Versafitcup CC TRIO

The Versafitcup CC Trio and the Versafitcup CC Trio No-Hole 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.

• Quadra-P and Quadra-P Collared

The hip prosthesis Quadra-P and Quadra-P Collared are designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. The Quadra-P Cemented is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

• Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

• AMIStem-H, AMIStem-H Collared, AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared

The hip prosthesis AMIStem-H, AMIStem-H collared, AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared are designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. The AMIStem-C is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.

Hip Replacement is indicated in the following cases:

• Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

• MiniMAX

The MiniMax is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

• Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement

arthroplasty, or total hip replacement.

• Quadra-H and Quadra-R
The hip prosthesis Quadra -S, Quadra-H and Quadra-R is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. The hip prosthesis Quadra-C is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:
• Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
The Quadra-C size 0 implant should not be implanted in patients with a mass of 65 kg or greater.

• SMS and SMS Collared
The hip prosthesis SMS and SMS Collared are designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:
• Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

• Mpres
The Mpres stem is a cementless neck preserving stem designed for use in total or partial hip arthroplasty for primary or revision surgery.
Total Hip Arthroplasty with the Mpres stem 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.
• Failure of previous hip surgery:
• Conservative hip surgery,
• Internal fixation,
• Arthrodesis,
• Hip resurfacing replacement.
Partial hip arthroplasty with the Mpres stem is indicated in the following cases:
• Acute traumatic fracture of the femoral head.
• Avascular necrosis of the femoral head.
• Primary pathology involving the femoral head but with a non-deformed acetabulum.

• Mpact Acetabular Shell
The Mpact 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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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, Regulatory, and Clinical Research, Medacta USA
Date Prepared: February 18, 2025
Date Revised: September 18, 2025

II. Device

Device Proprietary Name:	Coated hip implants
Common or Usual Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code	LZO
Secondary Product Code	LPH
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3358
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Medacta International SA, Versafitcup® CC Trio, K103352;

Additional Predicate devices:

- Medacta International SA, Versafitcup CC Trio extension, K122911;
- Medacta International SA, Quadra P, K181254;
- Medacta International SA, Quadra-P, K192827;
- Medacta International SA, Quadra-P, K202730;
- Medacta International SA, AMIStem-H Proximal Coating, K161635;
- Medacta International SA, AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared, K173794;
- Medacta International SA, AMIStem-P Short Neck, K192126;

- Medacta International SA, MiniMAX, K170845;
- Medacta International SA, MiniMAX, K192352;
- Medacta International SA, SMS Femoral Stem, K181693;
- Medacta International SA, SMS Cementless Stem, K201673;
- Medacta International SA, SMS Cementless Stem, K203041;
- Medacta International SA, Mpres Neck Preserving Stem, K210263;
- Medacta International SA, Medacta Total Hip Prothesis System-AMIStem H, Quadra S And Quadra H femoral stems, K093944;
- Medacta International SA, AMIStem and Quadra - Line Extension, K121011;
- Medacta International SA, Medacta Total Hip Prosthesis System – Quadra J, Quadra R, K082792;
- Medacta International SA, Mpact® Acetabular System, K103721;
- Medacta International SA, Mpact Extension, K122641;
- Medacta International SA, Mpact Extension, K132879;
- Medacta International SA, Mpact Extension, K230011.

IV. Device Description

The aim of this submission is to seek clearance for the addition of a new coating supplier for the following coatings:

- Titanium + Hydroxyapatite coating;
- Hydroxyapatite coating;
- Porous Titanium coating for Mpact devices; and
- Titanium coating for Mpact T sizes devices.

The already FDA cleared devices affected by the change are listed in **Table 1** below.

Table 1: FDA cleared devices impacted by the change.

510k	Product name	Substrate material	Coating
K103352 K122911	Versafitcup CC TRIO	Ti-6Al-4V (ASTM F136)	Titanium + Hydroxyapatite
K181254 K192827 K202730	Quadra-P Quadra-P Collared Quadra-P Short Neck	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite
K161635 K173794	AMIStem-H Proximal Coating	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite
K173794 K192126	AMIStem-P AMIStem-P Collared AMIStem-P Short Neck	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite
K170845 K192352	MiniMAX	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite
K181693 K201673	SMS	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite

510k	Product name	Substrate material	Coating
K203041	SMS Collared	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite
K210263	Mpres	Ti-6Al-7Nb (ISO 5832-11)	Titanium + Hydroxyapatite
K093944	AMIStem-H	Ti-6Al-7Nb (ISO 5832-11)	Hydroxyapatite
K121011	AMIStem-H Collared		
K082792	Quadra-H	Ti-6Al-7Nb (ISO 5832-11)	Hydroxyapatite
K093944	Quadra-H Short Neck		
K121011			
K082792	Quadra-R	Ti-6Al-7Nb (ISO 5832-11)	Hydroxyapatite
K103721	Mpact Acetabular Shell	Ti-6Al-4V (ASTM F136)	Porous Titanium
K122641			
K132879			
K230011			Porous Titanium / Titanium

V. Indications for Use

- *Versafitcup CC TRIO*

The Versafitcup CC Trio and the Versafitcup CC Trio No-Hole 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.

- *Quadra-P and Quadra-P Collared*

The hip prosthesis Quadra-P and Quadra-P Collared are designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. The Quadra-P Cemented is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

- *AMIStem-H, AMIStem-H Collared, AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared*

The hip prosthesis AMIStem-H, AMIStem-H collared, AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared are designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. The AMIStem-C is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.
Hip Replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

- *MiniMAX*

The MiniMax is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

- *Quadra-H and Quadra-R*

The hip prosthesis Quadra -S, Quadra-H and Quadra-R is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. The hip prosthesis Quadra-C is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

The Quadra-C size 0 implant should not be implanted in patients with a mass of 65 kg or greater.

- *SMS and SMS Collared*

The hip prosthesis SMS and SMS Collared are designed for cementless use in total or partial hip arthroplasty in primary or revision surgery. Hip Replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

- *Mpres*

The Mpres stem is a cementless neck preserving stem designed for use in total or partial hip arthroplasty for primary or revision surgery.
Total Hip Arthroplasty with the Mpres stem 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.
- Failure of previous hip surgery:
- Conservative hip surgery,
- Internal fixation,
- Arthrodesis,
- Hip resurfacing replacement.

Partial hip arthroplasty with the Mpres stem is indicated in the following cases:

- Acute traumatic fracture of the femoral head.
- Avascular necrosis of the femoral head.
- Primary pathology involving the femoral head but with a non-deformed acetabulum.

- *Mpact Acetabular Shell*

The Mpact 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 Indications for Use and technological characteristics

The subject hip implants with the coating performed by the new supplier are substantially equivalent to the predicate devices.
The only modification of the previously cleared orthopedic devices is the addition of an alternate supplier to administer the coating process. The devices design, principle of operation, substrate material, dimensional characteristics, indications for use, biocompatibility, packaging, shelf life and sterility will not change as a result of the implementation of an alternate coating supplier.

VI. Performance Data

Validation and testing were conducted according to test protocols to provide a detailed characterization of the coating performed by the new supplier and to demonstrate the substantial equivalence between the coatings performed by the new supplier and the ones performed by the current coating supplier, thus the substantial equivalence between the subject devices coated by the new coating supplier and the predicate devices coated by the current coating supplier.
The analysis and evaluations on the coating and on the subject coated products, performed according to standard's requirements, show that they meet the corresponding acceptance criteria and that the devices coated by new coating supplier are validated, they can be considered safe and effective for their intended use and substantially equivalent to the predicate devices.

Non-Clinical Studies

- *COATING CHARACTERIZATION*
  - Evaluation of the composition of the coating powders and of the coating performed by the new supplier on coupons according to ISO 13179-1, ISO 13779-2 and ISO 13779-3;
  - Evaluation of the mechanical properties and morphology of the coating performed by the new supplier on coupons according to ASTM F1854, ASTM F1147, ASTM F1609, ASTM F1044, ASTM F1160, ASTM F1978, ISO 21920-3 and ISO 13779-4;

- *COATED PRODUCT CHARACTERIZATION*
  - Evaluation of the coating characteristics on the coated final products or on coupons coated with the devices' production batch according to ASTM F1854, ASTM F1609 and ISO 21920-3;
  - Evaluation of the mechanical properties of the final coated products according to ASTM F3090-20;

- *CLEANING* evaluation according to ISO 19227

- *BIOCOMPATIBILITY* assessment according to ISO 10993 series

- *SHELF-LIFE* evaluation including subject devices packaging validation according to ISO 11607-1 and ISO 11607-2

Clinical Studies:

- No clinical studies were conducted.

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