July 22, 2022

Medacta International S.A.
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K211891
Trade/Device Name: DM Converter - TiN coated
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, MEH
Dated: June 24, 2022
Received: June 27, 2022

Dear Chris 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 (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 located 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.

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

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

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)*

K211891

Device Name

DM Converter – TiN coated

Indications for Use *(Describe)*

The Medacta DM Converter is designed to be used in combination with the Mpact and Versafitcup CC Trio family cementless cups in total hip arthroplasty in primary or revision surgery.

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

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

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: June 17, 2021
Date Revised: July 22, 2022

II. Device

Device Proprietary Name:	DM Converter – TiN coated
Common or Usual Name:	Total Hip Prosthesis
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code:	LZO
Secondary Product Code	MEH
Regulation Number:	21 CFR 888.3353
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Mpact DM Converter, K131458, Medacta International SA

In addition, the following reference devices are cited within the submission:

- Mpact Double Mobility System, K143453, Medacta International SA
- Versafitcup DM, K083116 and K092265, Medacta International SA
- OMNI TiN Coated Apex Knee™ System, K191765, OMNI Life Science, Inc.
- Biocore9 Humeral Resurfacing System, K193122, Biocore9, LLC.

IV. Device Description

The purpose of this submission is to gain clearance for the new DM Converter – TiN coated Implants and to extend the shell's compatibility of the already cleared DM Converter (K131458). Specifically, both the new DM Converter – TiN coated and the already cleared DM Converter (K131458) can be

coupled with Mpact (K103721, K122641, K132879 and K171966) and Versafitcup CC Trio Family shells (K103352 and K121911).

The DM Converter – TiN coated is a line extension to the DM Converter (K131458) to provide a larger product offering.

The DM Converter – TiN coated is a component of a total hip joint prosthesis that is used to replace the acetabulum in both primary or revision surgery. It is a highly polished metal liner made of High Nitrogen Stainless Steel according to ISO 5832-9 with a TiN coating on the external surface.
The DM Converter – TiN coated is inserted into the acetabular shell and can be coupled with a mobile liner: Medacta Double Mobility UHMWPE (ISO 5834-2 Type 1) liners (K083116 and K131458) or HighCross (highly crosslinked UHMWPE) liners (K092265 and K131458).

The DM Converter – TiN coated is available in 6 six sizes with a nomenclature that identifies the cup liner size (first letter) and the double mobility liner size (final three letters): D/DMB, E/DMC, F/DME, G/DMF, J/DMH and K/DML.

V. Indications for Use

The Medacta DM Converter is designed to be used in combination with the Mpact and Versafitcup CC Trio family cementless cups in total hip arthroplasty in primary or revision surgery.
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

VI. Comparison of Technological Characteristics

The DM Converter – TiN coated and the predicate device, Mpact DM converter (K131458), share the following characteristics:

- sizes;
- indications for use
- shape and design (except for the lateralization and groove for coating limit);
- modular connection fixation;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The subject DM Converter – TiN coated differs from the predicate device, Mpact DM converter (K131458), with respect to:

- lateralization of both articulating surface and edge;
- groove for coating limit; and
- material and coating.

Discussion
Medacta International SA has not made any change to the indications for use, device usage, device sizes biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
  - DM Converter TiN coated, Validation Workshop and Evaluation forms

- *PERFORMANCE TESTING*
  - DM Converter – TiN coated – Stability test according to *ASTM F1820-13 Standard Test Method For Determining the Forces for Disassembly of Modular Acetabular Devices*
  - DM Converter – TiN coated – Fretting corrosion test
  - DM Converter – TiN coated - Jumping distance and ROM evaluation rationale
  - DM Converter – TiN coated - Wear test according to *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 [Including AMENDMENT 1 (2018)]*
  - Taber test according to *ASTM 1978-18 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser*
  - Adhesive shear strength through scratch testing according to *ISO 20502 Fine ceramics (advanced ceramics, advanced technical ceramics) - Determination of adhesion of ceramic coatings by scratch testing*
  - Double Mobility Converter Implants Compatibility Extension 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 DM Converter – TiN coated is substantially equivalent to the predicate device.