June 13, 2025

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

Re: K251166
Trade/Device Name: Mfinity Femoral System
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: MEH, LZO, KWY, KWL, LPH
Dated: April 15, 2025
Received: April 15, 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,

RYAN TROMBETTA -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)*
K251166

Device Name
Mfinity Femoral System

Indications for Use *(Describe)*
Mfinity femoral stems are indicated in patients requiring hip arthroplasty.

Hip Arthroplasty
Total or partial hip arthroplasty is indicated in the following cases:
• Severely painful and/or disabled joint as a result of osteoarthritis, post-traumatic arthritis, inflammatory arthritis or hip dysplasia.
• Avascular necrosis of the femoral head.
• Acute fracture of the femoral head.
• Acute fracture of the proximal femur, suitable to be treated by means of hip arthroplasty.
• Non-union of proximal femur fracture, suitable to be treated by means of hip arthroplasty.
• Primary pathology involving the femoral head but with a non-deformed acetabulum.
• Failure of previous hip surgery:
o Conservative hip surgery.
o Internal fixation.
o Arthrodesis.
o Partial or total hip arthroplasty.
o Hip resurfacing replacement.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

I. Submitter

Medacta International SA
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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: April 15, 2025
Date Revised: June 13, 2025

II. Device

Device Proprietary Name:	Mfinity Femoral System
Common or Usual Name:	Total Hip Prosthesis
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code	MEH
Secondary Product Code	LZO, KWY, KWL, LPH
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390, 21 CFR 888.3360, 21 CFR 888.3358
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- Actis DuoFix Hip Prosthesis- Collarless, K210581, DePuy Ireland UC

Additional Predicate devices:

- DePuy Actis DuoFix Hip Prosthesis, K160907, DEPUY ORTHOPAEDICS, INC
- DePuy Actis Duofox Hip Prosthesis, K150862, DEPUY ORTHOPAEDICS, INC
- Quadra-P, K192827, Medacta International SA
- Quadra-P, K181254, Medacta International SA
- AMIStem-P, K173794, Medacta International SA

Reference devices:

- Masterloc, K151531, Medacta International SA
- GMK Sphere & GMK SpheriKA Cementless, K223548, Medacta International SA

IV. Device Description

The Mfinity Femoral System includes implantable devices provided individually packed, sterile and single-use intended for cementless use in total or partial hip arthroplasty to replace the native femoral neck for primary or revision surgery. The product range is composed of three different versions (Mfinity collarless, Mfinity collared and Mfinity L) available in standard and lateral offset.

The Mfinity femoral stem can be combined with the CoCr ball head (K072857, K080885 and K103721), Endo Head (K111145), the MectaCer BIOLOX® forte (K073337), MectaCer BIOLOX® Delta Femoral Heads (K112115) or MectaCer BIOLOX® Option Heads (K131518).

The subject devices are made of titanium alloy according to ISO 5832-11 and coated with Titanium plasma spray according to ASTM F1580 and Hydroxyapatite according with ASTM F1185.

V. Indications for Use

Mfinity femoral stems are indicated in patients requiring hip arthroplasty.

Hip Arthroplasty

Total or partial hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint as a result of osteoarthritis, post-traumatic arthritis, inflammatory arthritis or hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute fracture of the femoral head.
- Acute fracture of the proximal femur, suitable to be treated by means of hip arthroplasty.
- Non-union of proximal femur fracture, suitable to be treated by means of hip arthroplasty.
- Primary pathology involving the femoral head but with a non-deformed acetabulum.
- Failure of previous hip surgery:
    - Conservative hip surgery.
    - Internal fixation.
    - Arthrodesis.
    - Partial or total hip arthroplasty.
    - Hip resurfacing replacement.

VI. Comparison of Technological Characteristics

The subject and predicate devices (K150862, K160907, K210581) are substantially equivalent with respect to the following characteristics:

- Range of product;
- Taper;
- Fixation;
- Biocompatibility;
- Device usage;
- Packaging; and
- Sterilization.

The subject devices differ from the predicate devices (K150862, K160907, K210581) with respect to:

- CCD angle;
- Stem length;
- Neck offset; and

- Materials.

Discussion
The different CCD angles between the subject and predicate devices (K150862, K160907, K210581) does not affect safety and effectiveness since the subject devices' CCD angles are shared with Medacta predicate devices (K192827, K181254).
The partially different stem lengths between the subject and predicate devices (K150862, K160907, K210581) do not introduce any new risk of safety and effectiveness since they are included in the stem lengths of Medacta predicate devices: AMIStem-P (K173794) for the smaller lengths and Quadra-P (K192827, K181254) for the longer lengths.
Slightly bigger neck offset of the subject Mfinity L does not arise any new issue with respect to safety and effectiveness as demonstrated by mechanical evaluations.
The different material of the subject and predicate devices does not introduce new questions of safety and effectiveness since both the substrate material and the Titanium coating of the subject devices are shared with the additional predicate device, Masterloc (K151531).

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 VALDATION*
  - Mfinity Design Validation

- *PERFORMANCE TESTING*
  - Mfinity Fatigue tests according to ISO 7206-4 and ISO 7206-6
  - Pull-Off Test On CoCr Femoral Head
  - Evaluation of ROM according to ISO 21535
  - Cross sectioned area of the double coated implant surfaces of the Medacta Mfinity stem
  - Scanning Electron Microscopy pictures of the double coated implant surfaces of the Mfinity stem
  - XRD analyses comparing features of the HA coating deposed on the Medacta Mfinity stem and on planar samples made of Ti6Al7Nb

- *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.