Medacta International SA
% Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

January 9, 2020

Re: K193433
Trade/Device Name: AMIStem-C
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, JDI
Dated: December 10, 2019
Received: December 10, 2019

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,

Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193433

Device Name
AMIStem-C

Indications for Use *(Describe)*
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, for primary or revision surgery. The hip prosthesis 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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3.0 510(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 Affairs and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: December 10, 2019
Date Revised: January 3, 2020

II. Device

Device Proprietary Name:	AMIStem-C
Common or Usual Name:	Femoral Stem
Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Primary Product Code:	LZO
Secondary Product Codes:	JDI
Regulation Number:	21 CFR 888.3353
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Medacta Total Hip Prosthesis System – AMIStem C & QUADRA C Short Neck, K103189, Medacta International SA

- The following device is referenced in the submission: AMIStem-P stems K173794, Medacta International

IV. Device Description

AMIStem-C is a straight triple tapered cemented femoral stem of rectangular cross-section, for use in total or partial hip arthroplasty for primary or revision surgery. The material is High Nitrogen Stainless steel in accordance with ISO 5832-9.

Its superficial feature is a mirror polishing on the neck and the body: the whole body is mirror polished in order to minimize the wear due to the occasional contact between neck and cup, particularly in case of double-mobility cups, and to optimize the load transfer from stem to cement avoiding the stress shielding.

The AMIStem-C femoral stem size 00 is a line extension to the stems to the currently marketed Amistem-C product line.

V. Indications for Use

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, for primary or revision surgery. The hip prosthesis 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 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 subject AMIStem-C femoral stem and the predicate AMIStem-C femoral stems are identical with respect to materials of construction, surface finish, biocompatibility, device usage, sterility, shelf-life, and packaging.

The subject AMIStem-C femoral stem provides a smaller stem length and neck offset than the currently available AMIStem-C femoral stems. These differences do not introduce a new worst case from a clinical point of view or with respect to the biomechanical performance of the implants.

VII. Performance Data

The introduction of the AMIStem-C size 00 standard femoral stem does not create a new worst case; therefore, the following performance testing from the predicate device was leveraged to support this submission:

- neck fatigue testing per ISO 7206-4:2010;
- shaft fatigue testing per ISO 7206-6:2013;
- Range of Motion (ROM) Evaluation
- Bacterial Endotoxin Testing (LAL test and USP <151>);
- sterilization validation; and
- shelf-life testing.

VIII. Conclusion

The information provided within this submission supports that the AMIStem C size 00 standard femoral stem is as safe and effective as the predicate device; therefore, the AMIStem-C is substantially equivalent to the predicate device.