March 14, 2018

Medacta International SA
% Elizabeth Rose
Manager, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K173794
Trade/Device Name: AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared
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, KWY, LZY, LPH
Dated: December 13, 2017
Received: December 14, 2017

Dear Elizabeth Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K173794

Device Name
AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared

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

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Date Prepared: December 13, 2017
Date Revised: March 9, 2018

II. Device

Device Proprietary Name:	AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared
Common or Usual Name:	Femoral Stems
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code:	LZO, MEH, KWY, LZY, 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 devices:

- Medacta Total Hip Prosthesis – AMIStem H, Quadra S and Quadra H femoral stems, K093944, Medacta International SA
- AMIStem and Quadra – Line Extension, K121011, Medacta International SA
- AMIStem-H Proximal Coating, K161635, Medacta International SA

IV. Device Description

The AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared implants are line extensions to the Medacta Total Hip Prosthesis system family AMIStem H, Quadra S and

Quadra H femoral stems (K093944), AMIStem C & Quadra C SN (K103189), AMIStem and Quadra – Line Extension (K121011), and AMIStem-H Proximal Coating (K161635).

The AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared implants subject of this submission are comprised of the following products:

- AMIStem-H Proximal Coating STD, Stem sizes 00 and 0;
- AMIStem-H Proximal Coating LAT, Stem size 0;
- AMIStem-P STD, Stem sizes 00 – 9;
- AMIStem-P LAT, Stem sizes 0 – 8;
- AMIStem-P Collared STD, Stem sizes 00 – 9; and
- AMIStem-P Collared LAT, Stem sizes 0 – 8.

The AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared implants are part of the brand, Medacta Total Hip Prosthesis system for total and partial hip arthroplasty. The Medacta Total Hip Prosthesis system family consists of femoral stems, modular femoral heads, and acetabular components.

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 AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared implants and the predicate devices share the following characteristics:

- sizes;
- stem lengths;
- CCD angle;
- cementless;
- material of construction;
- coatings;
- coating composition of the AMIStem-H Proximal Coating only;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The only technological characteristic difference between the AMIStem-H proximal Coating and the predicate devices is the addition of three new sizes STD 00, 0 and LAT 0.

The only technological characteristic difference between the AMIStem-P and AMIStem-P Collared implants and the predicate devices is the coating composition. The AMIStem-P and AMIStem-P Collared implants have a double coating of Ti and HA in the proximal zone of the shaft and a HA coated distal end.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies

- Performance Tests
    - range of motion (ROM): EN ISO 21535:2009 Non-Active Surgical Implants — Joint Replacement Implants — Specific Requirements for Hip-Joint Replacement Implants (ISO 21535:2007/Amendment 1:2016);
    - fatigue testing: ISO 7206-4 Third Edition 2010-06-15 Implants For Surgery - Partial And Total Hip Joint Prostheses - Part 4: Determination Of Endurance Properties And Performance Of Stemmed Femoral Components [Including AMENDMENT 1 (2016)];
    - fatigue testing: ISO 7206-6 Second Edition 2013-11-15 Implants For Surgery - Partial And Total Hip Joint Prostheses - Part 6: Determination Of Endurance Properties Of Head And Neck Region Of Stemmed Femoral Components; and

- pull off force testing: ASTM F2009-00 (Reapproved 2011) Standard Test Method For Determining The Axial Disassembly Force Of Taper Connections Of Modular Prostheses.

- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted and met the endotoxin limit of <20 EU/device; and
  - Medacta has no intentions of labeling the subject devices as non-pyrogenic or pyrogen free.

VIII. Conclusion

Based on the above information, the AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared implants are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared implants are as safe and effective as the predicate devices, Medacta Total Hip Prosthesis – AMIStem H, Quadra S and Quadra H femoral stems (K093944), AMIStem and Quadra – Line Extension (K121011), and AMIStem-H Proximal Coating (K161635).

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