November 22, 2019

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

Re: K192126
Trade/Device Name: AMIStem-P Short Neck
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: October 22, 2019
Received: October 23, 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)*
K192126

Device Name
AMIStem-P Short Neck

Indications for Use *(Describe)*
The hip prosthesis 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 and Compliance Director, Medacta International SA
Date Prepared: August 5, 2019
Date Revised: November 20,2019

II. Device

Device Proprietary Name:	AMIStem-P Short Neck
Common or Usual Name:	Femoral Stems
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code:	LZO
Secondary Product Codes:	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 device:

- AMIStem-H Proximal Coating, AMIStem-P, and AMIStem-P Collared, K173794, Medacta International SA

IV. Device Description

The AMIStem-P Short Neck femoral stems are line extensions to the AMIStem-P femoral stems cleared under K173794.

The devices subject to this 510(k) are comprised of the following products:

- AMIStem-P Short Neck STD, Stem sizes 00 to 9, and
- AMIStem-P Short Neck LAT, Stem sizes 0 to 8.

The AMIStem-P Short Neck femoral stems are cementless stems manufactured from titanium-niobium alloy (Ti-6Al-7Nb alloy) and are coated with titanium and HA.

V. Indications for Use

The hip prosthesis 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-P Short Neck femoral stems and the predicate devices share the following characteristics:

- CCD angle;
- cementless;
- material of construction;
- coating and coating composition;
- biocompatibility;
- device usage
- sterility;
- shelf life; and
- packaging.

The AMIStem-P Short Neck femoral stems are technologically different from the predicate devices with respect to:

- neck offset; and
- lengths.

Discussion

As seen above, the AMIStem-P Short Neck femoral stems are substantially equivalent to the predicate device in terms of design; substrate material; coating; device usage; sterility; shelf life; and packaging.

The only difference between the subject and predicate devices is the smaller neck offsets and lengths. 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 predicate AMIStem-P femoral stem devices (K173794) were tested using the worst-case device for each of the following tests:

- range of motion (ROM): EN ISO 21535:2009 Non-Active Surgical Implants — Joint Replacement Implants — Specific Requirements for Hip-Joint Replacement Implants;
- 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 testing was conducted using the Bacterial Endotoxin Test (LAL test) and met the endotoxin limit of < 20 EU/device.

The subject devices do not represent a new worst case when compared to the previously cleared devices (K173794).

The data and information provided in K173794 support the conclusion that the AMIStem-P Short Neck femoral stems are substantially equivalent and conform to applicable standards and FDA guidance.

VIII. Conclusion

Based on the above information, the AMIStem-P Short Neck femoral stems can be considered substantially equivalent to the identified predicate device.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The AMIStem-P Short Neck femoral stems are substantially equivalent to the predicate devices, Medacta's AMIStem-P femoral stems.