'MENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 31, 2017

Medacta International SA
Stefano Baj
Regulatory Affairs Manager
Strada Regina
6874 Castel San Pietro (CH)
Switzerland

Re: K161635
Trade/Device Name: AMIstem-H Proximal Coating
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: February 28, 2017
Received: March 1, 2017

Dear Mr. Stefano Baj:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161635

Device Name

AMIStem-H Proximal Coating

Indications for Use *(Describe)*

The hip prosthesis AMIStem-H, AMIStem-H Collared, AMIStem-H Proximal Coating are designed for cementless use in total or partial hip arthroplasty in 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 arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip 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.

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510(k) Summary

I. Submitter

Medacta International SA
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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: March 28, 2017

II. Device

Device Proprietary Name:	AMIStem-H Proximal Coating
Common or Usual Name:	Femoral Stems
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number(s):	21 CFR 888.3353, 21 CFR 888.3390, 21 CFR 888.3360, 21 CFR 888.3358
Product Code:	LZO, MEH, KWY, LZY, LPH
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- Medacta Total Hip Prosthesis – AMIStem H, Quadra S and Quadra H femoral stems, K093944, Medacta International SA

Additional Predicates:

- *Avenir*® Müller Stem, K123392, Zimmer GmbH

Reference Device:

- AMIStem and Quadra – Line Extension, K121011, Medacta International SA

IV. Device Description

The AMIStem-H Proximal Coating femoral stems are line extensions to the Medacta Total Hip Prosthesis system and are comprised of the following products:

- AMIStem-H Proximal Coating STD, Stem #s 1 - 9
- AMIStem-H Proximal Coating LAT, Stem #s 1 - 8

These prostheses are straight femoral stems manufactured from titanium (Ti) alloy (ISO 5832-11:1994, Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminum 7-niobium alloy). The subject devices have a titanium and hydroxyapatite dual layer coating at the proximal end of the shaft and a sandblasted surface at the distal end.

The instruments used with the AMIStem-H Proximal Coating stems were previously cleared as part of the AMIStem Implants family (K093944, K103189, and K121011). Additional instrumentation, included within the subject 510(k), can be used in lieu of the previously cleared instruments.

V. Indications for Use

The hip prosthesis AMIStem-H, AMIStem-H Collared, AMIStem-H Proximal Coating are designed for cementless use in total or partial hip arthroplasty in 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 arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement

VI. Comparison of Technological Characteristics

The design features, and materials of the subject devices are substantially equivalent to those of the predicate devices.

The AMIStem-H Proximal Coating and the predicate devices share the following characteristics:

- Same materials of construction
- Same sizes (stem length and neck offset)
- Same product design (shape and macrostructures)

- Similar titanium and hydroxyapatite double coating as seen in the *Avenir*® Müller Stem
- Same sterilization method

The AMIStem-H Proximal Coating femoral stems are technologically different from the predicate devices in that the subject devices are double coated at the proximal end of the femoral stem whereas the entire surface of the *Avenir*® Müller Stems, with the exception of the polished neck area, is double coated.

A comparison of the subject and predicate devices is provided in the table below.

Technological comparison

	Subject Device	**Medacta Total Hip Prosthesis – AMIStem H, Quadra S & Quadra H Femoral Stems (K093944)**	***Avenir*® Müller Stem, (K123392)**
Material of Construction	Titanium alloy (ISO 5832-11)	Same	Titanium alloy
Coating	Titanium (ASTM F1580) Hydroxyapatite (ASTM F1185)	- Hydroxyapatite (ASTM F1185)	Titanium + Hydroxyapatite
Sizes	STD Stem #s 1 – 9 LAT Stem #s 1 - 8	STD Stem #s 0 – 9 LAT Stem #s 1 - 8	STD Stem #s 1 – 9 LAT Stem #s 1 – 9
Stem Shape	Straight and symmetrical	Same	Same
Macrostructures	Horizontal grooves in the proximal stem	Same	Same
	Vertical grooves in the distal stem	Same	Same
Sterilization Method	Gamma Irradiation	Same	Same
Device Usage	Single Use	Same	Same

Discussion

As seen above, the fundamental scientific technology of the subject devices has not changed relative to the predicate devices.

VII. Performance Data

The following performance data were provided or leveraged in support of the substantial equivalence determination.

Non-Clinical Studies

- Fatigue testing in accordance with ISO 7206-4:2010 and ISO 7206-6:1992
- Range of Motion Analysis in accordance with EN ISO 21535:2009
- Tilting and Rotation Stability
- Pull Off Testing in accordance with ASTM F2009-00
- Coating Tests
- Cleaning and Sterilization Validation
- Bacterial endotoxin testing
- Shelf-life studies

VIII. Conclusion

The information provided above supports that the AMIStem H-Proximal Coating is as safe and effective as the predicate devices. Although minor differences in design and technology exist between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the AMIStem-H Proximal Coating is substantially equivalent to the predicate devices.

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