April 12, 2022

Medacta International S.A.
℅ Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K220405
Trade/Device Name: Amis K Long
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, MEH, KWY
Dated: February 10, 2022
Received: February 14, 2022

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,

Limin Sun, Ph.D.
Acting 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)*
K220405

Device Name
Amis K Long

Indications for Use *(Describe)*
The hip prosthesis AMIS-K Long is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.

Total 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.
Partial hip arthroplasty is indicated in the following cases:
• Acute traumatic fracture of the femoral head or neck
• Non-union of femoral neck fracture
• Avascular necrosis of the femoral head.
• Primary pathology involving the femoral head but with a non-deformed acetabulum.

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

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA Applicant
Correspondent: Chris Lussier, Sr. Director, Quality, Regulatory, and Clinical, Medacta USA
Date Prepared: February 10, 2022
Date Revised: April 12, 2022

II. Device

Device Proprietary Name:	Amis K Long
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	JDI, MEH, KWY
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3350, 21 CFR 888.3390
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Quadra-P Cemented, K192827, Medacta International SA

Additional predicate device:

- M-Vizion K201471, Medacta International SA
- Quadra C, K083558, Medacta International SA
- Arcos, K100469, Biomet

IV. Device Description

The AMIS-K Long cemented stem is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.
The AMIS-K Long is a straight, double-tapered cemented stem whose primary stability is ensured by bone cement.

The AMIS-K Long implants in this submission are comprised of the following size: from #2 to #5 with 2 different stem body size for #2, #3 and #4, 1 different stem body size for #5. Stem length: 200 – 250 – 300 mm (for each size).

The AMIS-K Long implants are part of the Medacta Total Hip Prosthesis system.
The Medacta Total Hip Prosthesis system consists of femoral stems, modular femoral heads, and acetabular components.

The AMIS-K Long are cemented stems manufactured from high nitrogen stainless steel (ISO 5832-9) with a mirror polished surface.

The acetabular components consist of metal cups and liners made of ultra-high molecular weight polyethylene (UHMWPE), or Highcross highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE). Acetabular components include the Mpact DM (K143453), VersafitCup (K083116 and K092265), VersafitCup CC Trio (K103352, K120531 and K122911), Mpact (K103721 and K132879), Mpact 3D Metal (K171966), and Medacta Bipolar Head (K091967).

The AMIS-K Long implants can be combined with the CoCr Ball Heads (K072857 and K080885), Endo Head (K111145), or MectaCer BIOLOX® Forte (K073337) or MectaCer BIOLOX® Delta Femoral Heads (K112115).

V. Indications for Use

The hip prosthesis AMIS-K Long is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.

Total hip arthroplasty 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.

Partial hip arthroplasty is indicated in the following cases:

- Acute traumatic fracture of the femoral head or neck
- Non-union of femoral neck fracture
- Avascular necrosis of the femoral head.
- Primary pathology involving the femoral head but with a non-deformed acetabulum.

VI. Comparison of Technological Characteristics

The subject Amis K Long implants and the predicate device Quadra-P cemented (K192827) share the following similarities:

- Intended use
- Cemented stem
- Femoral Stem Trunnion Geometry
- Materials
- Surface finish
- Same compatible acetabular systems

The main differences between the subject Amis K Long implants and the predicate device Quadra-P cemented (K192827) are:

- Stem design : Charnley-Kerboull stem VS straight, triple tapered with rectangular cross-section (Amis K Long VS Quadra-P cemented respectively)
- CCD (caput-collum-diaphyseal) angle : 130° VS 135°/127° (Amis K Long VS Quadra-P cemented respectively)
- Stem length

Comparison with additional predicate devices:
Medacta International SA has not made any change to, sterility and shelf life of the subject devices respect to the predicate device and the additional predicate device M-Vizion K201471.
The subject Amis K Long stem is similar in length to other cleared uncemented hip stems, such as Medacta M-Vizion (K201471) and Biomet Arcos Interlocking Distal Stems (K100469).

VII. Performance Data

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

Non-Clinical Studies:

- Performance Tests
  - Pull-Off: ASTM F2009-00 (Reapproved 2011) Test on CoCr Femoral Head according to Test Protocol IL 07.09.033, EndoLab Test Report, No.: 167.081021.10.1144, CeramTec AG Test Reports 3129 and 3300.
  - range of motion (ROM): *EN ISO 21535:2009 Non-Active Surgical Implants - JointReplacement 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*;

- Design Validation Protocol and workshop

- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination.
  - the subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the Amis-K Long 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 Amis K Long implants are as safe and effective as the predicate device.