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

September 18, 2020

Re: K201673
Trade/Device Name: SMS Cementless Stem
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
Dated: August 27, 2020
Received: August 28, 2020

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, M.S.
Assistant Director
DHTA: Division of Joints Arthroplasty
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)*

K201673

Device Name
SMS Cementless Stem

Indications for Use *(Describe)*

The hip prosthesis SMS is designed for cementless use in total or partial hip arthroplasty, for 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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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: June 18, 2020

II. Device

Device Proprietary Name:	SMS Cementless Stem
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
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390, 21 CFR 888.3360
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- Primary Predicate: Zimmer Porolock MIS Stem, K071723, Zimmer GmbH; and
- Additional Predicate: SMS, K181693, Medacta International SA.

IV. Device Description

The SMS femoral stem is a cementless bone preserving short stem designed for proximal fixation in total or partial hip arthroplasty for primary or revision surgery.

The SMS implants are comprised of the following products:

- SMS Cementless Solid Standard Stem (available in 11 sizes – from size 3 to 13); and
- SMS Cementless Solid Lateralized Stem (available in 11 sizes - from size 3 to 13).

Both are available on the US market via the clearance - K181693.

Concerning the new sizes of the solid version: 1V2, 2V2, size 14, and size 15; both STD and LAT versions have been introduced as a product range extension to the stems currently marketed as the SMS product line (K181693).

The SMS implants are line extensions to Medacta's Total Hip Prosthesis - AMIStem-H, Quadra-S and Quadra-H Femoral Stems (K093944), AMIStem and Quadra - Line Extension (K121011), AMIStem-P, AMIStem-P Collared and AMIStem-H Proximal Coating Femoral Stems (K173794), Quadra-H and Quadra-R Femoral Stems (K082792), AMIStem-H Proximal Coating (K161635), MiniMAX (K170845), and SMS (K181693).

The SMS 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 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), Mpact (K103721 and K132879), Mpact 3D Metal (K171966) and Medacta Bipolar Head (K091967).

The SMS stems can be combined with the CoCr ball heads (K072857, K080885 and K103721), Endo Head (K111145) or with the MectaCer BIOLOX® Forte (K073337), MectaCer BIOLOX® Delta Femoral Heads (K112115) or MectaCer BIOLOX® Option Heads (K131518).

V. Indications for Use

The hip prosthesis SMS is designed for cementless use in total or partial hip arthroplasty, for 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 SMS range extension implants and the predicate devices share the following characteristics:

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

SMS is technologically different from the predicate devices as follows:

- sizes;
- stem lengths;

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;
  - 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;
  - pull off force testing: ASTM F2009-00 (Reapproved 2011) Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses.
- Coating Tests
  - ISO 13779-1 Second Edition 2008-10-01 Implants for Surgery - Hydroxyapatite - Part 1: Ceramic Hydroxyapatite; and
  - ASTM F1147-99 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings.
- 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; and
  - the subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the SMS implants **new sizes 1V2, 2V2, size 14, and size 15 both STD and LAT version** 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 SMS range extension implants

are as safe and effective as the predicate devices, Zimmer Porolock MIS Stem (K071723) and SMS solid stem, (K181693).