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

December 7, 2017

Re: K173267
Trade/Device Name: MasterLoc™ Stem: Lateralized Plus
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, LPH, LZY
Dated: October 10, 2017
Received: October 11, 2017

Dear Ms. 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,

Katherine D. Kavlock -S

for
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)*

K173267

Device Name

MasterLoc™ Stem: Lateralized Plus

Indications for Use *(Describe)*

The hip prosthesis MasterLoc™ is designed for cementless 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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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 Affairs Manager, Medacta International SA
Consultant: Elizabeth Rose, Regulatory Affairs Manager, Medical Devices, Mapi USA, Inc.
Date Prepared: October 10, 2017
Revised: November 29, 2017

II. Device

Device Proprietary Name:	MasterLoc™ Stem: Lateralized Plus
Common or Usual Name:	Total Hip Prosthesis
Classification Name:	Hip joint metal/polymer semi-constrained cemented or nonporous uncemented prosthesis
FDA Product Code:	LZO, MEH, KWY, LPH, LZY
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390, 21 CFR 888.3358, 21 CFR 888.3360
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary Predicate:

- MasterLoc™ Stem, K151531, Medacta International SA
- MasterLoc™ Stem, K160289, Medacta International SA

Additional Predicates:

- Anthology Hip Stem, K052792, Smith & Nephew, Inc.

IV. Device Description

The MasterLoc™ Stem: Lateralized Plus implants are a line extension to Medacta's MasterLoc™ Stem product line (cleared under K151531 and K160289). The MasterLoc™ Stem: Lateralized Plus implants offer an additional caput-collum-diaphyseal (CCD) angle of 122° and neck offsets for various

patient anatomies. The MasterLoc™ Stem: Lateralized Plus implants include cementless, flat, dual tapered design stems intended for total hip arthroplasty in primary or revision surgery.

The MasterLoc™ Stem: Lateralized Plus implants are made with a titanium alloy substrate (Ti6Al7Nb) according to ISO 5832-11 Second Edition 2014-09-15: Implants for Surgery – Metallic Materials – Part 11: Wrought Titanium 6–Aluminium 7-Niobium Alloy. The surface treatment consists of Ti coating with a thickness of 700 μm in the proximal 2/3 of the shaft to improve proximal fixation. The distal portion of the stems are uncoated with a satin finish obtained from glass bead blasting.

The MasterLoc™ Stem: Lateralized Plus implants are available in sizes 4 to 12, with a range of stem lengths from 126.5 mm to 147.5 mm. The stems have a Eurocone (12/14 taper with an angle of 5° 42' 30'') and the necks are polished.

V. Indications for Use

The hip prosthesis MasterLoc™ is designed for cementless 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 MasterLoc™ Stem: Lateralized Plus and the predicate devices share the following characteristics:

- sizes;
- lengths;
- taper;
- substrate material;
- coating;
- device usage;
- sterility;
- shelf life; and
- packaging.

The MasterLoc™ Stem: Lateralized Plus implants are technologically different from the predicate devices as follows:

- CCD angle, and
- neck offset.

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)]; and
  - 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.
- Pyrogenicity
  - the Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the 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 MasterLoc™ Stem: Lateralized Plus can be considered 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 MasterLoc™ Stem: Lateralized Plus implants are as safe and effective as the predicate devices, Medacta's MasterLoc™ Stem (K151531 and K160289) and Smith & Nephew's Anthology Hip Stem (K052792).