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

May 31, 2019

Re: K191145
Trade/Device Name: MasterLoc™ Extension
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, KWY, LPH, LZY
Dated: April 29, 2019
Received: April 30, 2019

Dear Chris Lussier:

This letter corrects our substantially equivalent letter of May 30, 2019**.**

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 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,

FOR: CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K191145

Device Name
MasterLoc Stem Extension

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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3.0 510(k) Summary

I. Submitter

Medacta International SA
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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Date Prepared: April 29, 2019
Date Revised: May 30, 2019

II. Device

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

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- MasterLoc™ Stem, K151531, Medacta International SA

Additional Predicates:

- MasterLoc™ Stem, K160289, Medacta International SA
  MasterLoc™ Stem: Lateralized Plus K173267, Medacta International SA

IV. Device Description

The MasterLoc™ Stem Extension is a line extension to Medacta's MasterLoc™ Stem product line (cleared under K151531; K160289 and K173267). The MasterLoc™ Stem Extension implants offer two additional and bigger sizes (sizes 13 and 14) to the product range currently on the market, for both the MasterLoc™ LAT (K151531 and K160289) and the MasterLoc™ LAT Plus (K173267) product lines. The MasterLoc™ Stem Extension implants have been designed with the same shape, design, and substrate material as the previously cleared MasterLoc™ Stem devices (K151531; K160289 and K173267).

The MasterLoc™ Stem Extension 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 in the proximal 2/3 of the shaft to improve proximal fixation. The distal portion of the stems are uncoated with a satin finish which is obtained from glass bead blasting.

The MasterLoc™ Stem Extension implants consist of two new additional sizes (13 and 14), with a stem length of 149,5 mm and 151,5 mm, respectively. The stems have a Eurocone (12/14 taper with an angle of 5°42'30'') and the necks are polished, as well as the above mentioned predicate devices.

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 Extension and the predicate devices share the following characteristics:
- taper;
- substrate material;
- coating;
- device usage;
- CCD angle;

- neck offset;
- sterility;
- shelf life; and
- packaging.

The MasterLoc™ Extension is technologically different from the predicate devices as follows:

- sizes; and
- lengths.

Discussion

As seen above, the MasterLoc™ Stem Extension implants are substantially equivalent to the predicate devices 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 new stem lengths (longer), that doesn't introduce any worst case from a clinical point of view or regarding the biomechanical performance of the implants. The new feature has been designed in order to increase the product range. This technological difference does not raise new questions of safety or effectiveness and a comparison evaluation shows there are no new risks associated with the subject device design.

Biocompatibility testing conducted on the Medacta's predicate devices MasterLoc™ Stems (cleared under K151531; K160289 and K173267) for the same materials support the biological safety of the MasterLoc™ Extension stems.

VII. Performance Data

- Engineering Rationale

  A comparative analysis of the subject devices to the identified predicate and reference devices was performed to determine if the longer stem body lengths created a new worst-case product size. It was determined that the subject stems are substantially equivalent to the previously cleared shorter stems in terms of mechanical strength as there is no change to the materials and moreover, the length of the neck is identical to the one of the size 12 of the MasterLoc™ LAT and the MasterLoc™ LAT Plus version, respectively. As the additional sizes do not represent a worst case for the any of the mechanical characteristic tested for the already cleared predicate devices, no additional mechanical testing or design validation was undertaken.

The subject devices do not represent a new worst case when compared to the previously cleared devices (K151531; K160289 and K173267).

The data and information provided in K151531; K160289 and K173267 support the conclusion that the MasterLoc™ Extension devices are substantially equivalent and conform to applicable standards and FDA guidance.

VIII. Conclusion

Based on the above information, the MasterLoc™ Stem Extension implants 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 Extension implants are substantially equivalent to the predicate devices, Medacta's MasterLoc™ Stems (cleared under K151531; K160289 and K173267).

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