DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 20, 2016

Medacta International SA
% Ms. Roshana Ahmed, MA, RAC
Sr. Manager, Regulatory Affairs - Medical Devices
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K160289
Trade/Device Name: MasterLoc 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, LPH, KWY, LZY
Dated: March 24, 2016
Received: March 24, 2016

Dear Ms. Roshana Ahmed:

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 yours,

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 on last page.

510(k) Number *(if known)*

K160289

Device Name

MasterLoc Stem

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Applicant/Sponsor: Medacta International SA
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Contact Person: Stefano Baj, Regulatory Affairs Manager

Date Prepared: March 21, 2016

Device Information
Trade/Proprietary Name: MasterLoc Stem
Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number: 21 CFR 888.3353
Device Class: Class II
Classification Product Code: LZO
Subsequent Product Codes: LPH, MEH, KWY, LZY

Predicate Device:

510(k)	Product	510(k) Holder	Clearance Date
K151531	MasterLoc Stem	Medacta International	10/30/15

Product Description

A hip prosthesis consists of a femoral stem made of metal, a modular femoral head made of metal or ceramic, and acetabular components. The acetabular components consists of a metal cup, and a liner that is made of ultra-high molecular weight polyethylene (UHMWPE), or Highcross highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE). Acetabular components can be: Versafitcup, Versafitcup CC Trio, Mpact, Medacta Bipolar Head.

All the auxiliary components of the prosthesis are supplied in single-use individual packages.

The MasterLoc® stems can be combined with the CoCr ball heads, Endo Head or with the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta femoral heads. Refer to the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta femoral heads package insert and to CoCr heads package insert for more information about ball heads.

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.

Comparison to Predicate Devices

The indications for use, design features and materials of the MasterLoc Stem are substantially equivalent to those of the predicate device. The substantial equivalence of the MasterLoc Stem is adequately supported by the information and analysis data provided within this Premarket Notification.

Purpose of Special 510(k)

The purpose of this Traditional 510(k) is to obtain clearance of MasterLoc sizes 1 – 3 using K151531 (MasterLoc sizes 4-12) as a predicate device.

Performance Testing

The modification to the device system to include the additional sizes of the MasterLoc Stem was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system.

The additional MasterLoc Stem sizes were compared to the worst case predicate device in accordance ISO 7206- 4:2010 (size 1 LAT with an XL ball head), while for ISO 7206-6:2013 the worst case remained the previous device already tested (size 12 LAT). The new test successfully met acceptance criteria.

The subject MasterLoc Stems have similar performance testing as the predicate in terms of:

RISK	STANDARD
Risk of breakage of highly stressed parts of the stem	ISO 7206-4 (2010) ISO 7206-6 (2013)
Limited ROM	EN ISO 21535 (2009)
Risk of implant loosening due to a low strength of the adhesion and durability of the coating.	Internal
Instability of the modular connection	ASTM F2009-00 (2009)
Instability of the modular connection	ASTM F2009-00 (2009)
Risk of inadequate selection of predicate device.	Internal
Risk of instability. Risk of bone breakage due to lateral opening.	Internal

Conclusion:
Based on the above information, the MasterLoc Stem can be considered as substantially equivalent to its predicate devices.