November 29, 2017

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

Re: K170690
Trade/Device Name: M-Vizion Femoral Revision System
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
Dated: October 30, 2017
Received: October 31, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170690

Device Name
M-Vizion Femoral Revision System

Indications for Use *(Describe)*
The hip prosthesis M-Vizion 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

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: March 6, 2017
Date Revised: November 21, 2017

II. Device

Device Proprietary Name:	M-Vizion Femoral Revision System
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:	KWY
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390
Device Classification	2

III. Predicate Device

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

- Revision Femoral Stem, K151739, Limacorporate S.p.A.
- Wagner SL Revision Stem Lateral, Wagner Cone Prosthesis® System, K161192, Zimmer GmbH

Reference Devices

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

IV. Device Description

The purpose of this submission is to gain clearance for the M-Vizion Femoral Revision System. The M-Vizion Femoral Revision System is a modular cementless stem intended to be used for hip arthroplasty in primary or revision surgery. The system is composed of the proximal body, the distal stem, and the locking screw. The proximal body and the distal stem are intended to be assembled together on a conical coupling and tightened by the locking screw.

The proximal body is made of titanium alloy and coated with a titanium coating, TiGrowth®-C (Medacta commercial name: Mectagrip). The distal stem is a straight stem made of titanium alloy and the principal feature consists of shard fins that potentially increase the rotation stability. The locking screw is made of titanium alloy and coated with TiNbN.

The M-Vizion Femoral Revision System is similar to competitor predicate devices Limacorporate S.p.A.'s Revision Femoral Stem (K151739), Zimmer GmbH's Wagner SL Revision Stem Lateral, Wagner Cone Prosthesis® System (K161192) and reference device Medacta's MasterLoc Stem (K151531 and K160289).

V. Indications for Use

The hip prosthesis M-Vizion 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 M-Vizion Femoral Revision System and the predicate devices share the following characteristics:

- indications for use;
- materials;
- design;
- sterile;
- coating; and
- device usage.

The M-Vizion Femoral Revision System is technologically different from the predicate devices as follows:

- sizes;
- lengths; and
- diameters.

VII. Performance Data

The following performance tests are being provided in support of a substantial equivalence determination. Testing was conducted to written protocols with acceptance criteria that were based on standards.

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;
    - shaft 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)];
        - modular conical connection fatigue test, and
        - post fatigue fretting corrosion analysis.
    - neck 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; and
    - coating characterization tests:
        - characterization report of titanium coating on Ti6Al7Nb substrates for orthopedic; and
        - characterization report of TiNbN coating on cobalt chrome, titanium alloy, and stainless steel substrates for orthopedic.
- Pyrogenicity
    - Bacterial Endotoxin Test (LAL test) was conducted and met the endotoxin limit of <20 EU/device; and
    - Medacta has no intentions of labeling the subject devices as non-pyrogenic or pyrogen free.

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the M-Vizion Femoral Revision System is as safe and effective as the predicate devices. Therefore, it is concluded that the M-Vizion Femoral Revision System is substantially equivalent to the predicate devices.

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