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

January 11, 2021

Re: K201471
Trade/Device Name: M-Vizion Femoral Revision System 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
Dated: December 22, 2020
Received: December 23, 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
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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)*

K201471

Device Name

M-Vizion Femoral Revision System Extension

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.

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 and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Sr. Director of Quality and Regulatory, Medacta USA
Date Prepared: June 3, 2020
Date Revised: January 4, 2021

II. Device

Device Proprietary Name:	M-Vizion Femoral Revision System Extension
Common or Usual Name:	Hip Prosthesis
Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Primary Product Code:	LZO
Secondary product code	KWY
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate:

- M-Vizion Femoral Revision System Extension, K191816, Medacta International SA

Reference predicate:

- M-Vizion Femoral Revision System, K170690, Medacta International SA
- Revision Femoral Stem, K151739, Limacorporate S.p.A.

IV. Device Description

The M-Vizion Femoral Revision System Extension implants are a range extension to the already cleared M-Vizion Femoral Revision System (K191816 and K170690). The range extension includes proximal bodies with holes and distal stems 4°.

The M-Vizion Femoral Revision System a is modular cementless stem intended to be used for hip arthroplasty, primary or revision. The system is composed of proximal body, distal stem and 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 locking screw provided with the subject proximal bodies is the same component cleared with the predicate devices, M-Vizion Femoral Revision System K191816 and K170690.

The proximal body is made of titanium alloy (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 and coated with a titanium coating, TiGrowth®-C (Medacta commercial name: Mectagrip). The distal stem is made of titanium alloy while the locking screw is made of titanium alloy and coated with TiNbN.

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 Extension implants and the predicate devices share the following characteristics:

- indication for use;
- system design;
- sizes;
- materials;
- coating;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The M-Vizion Femoral Revision System Extension implants differ from the predicate devices as follow:

- specific component shape
- final implant lengths

Discussion
Medacta International SA has not made any change to the indication for use, system design, materials, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.
The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject devices design, and supports the substantial equivalence of the M-Vizion Femoral Revision System Extension implants to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, design validation and characterization testing were conducted to written protocols. The following validation and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *DESIGN VALIDATION and CHARACTERIZATION TESTING*
  - M-Vizion Femoral Revision System - Design validation
  - M-Vizion Femoral Revision System - ROM evaluation
  - M-Vizion Femoral Revision System – Fatigue test of the shaft, neck and modular connection according to IL 07.09.187, worst case evaluations and Test Reports 00812-009683-1 and 00812-009683-2

- *PYROGENICITY:*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled 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 Extension implants are as safe and effective as the predicate devices. Therefore, it is concluded that the M-Vizion Femoral Revision System Extension implants are substantially equivalent to the predicate devices.