May 24, 2022

Medacta International S.A.
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K212327
Trade/Device Name: M-Vizion Monobloc
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: April 20, 2022
Received: April 22, 2022

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,

Limin Sun, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212327

Device Name
M-Vizion Monobloc

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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2.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: July 26, 2021
Date Revised: May 20, 2022

II. Device

Device Proprietary Name:	M-Vizion Monobloc
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, K201471, Medacta International SA

Secondary Predicate:

- M-Vizion Femoral Revision System Extension, K191816, Medacta International SA
- M-Vizion Femoral Revision System, K170690, Medacta International SA
- Wagner SL Revision Stem K953689, Zimmer Biomet
- Wagner SL Revision Stem Lateral K043356, Zimmer Biomet
- Wagner Cone Prosthesis System K113556, Zimmer Biomet

IV. Device Description

The M-Vizion Monobloc is a range extension to the already cleared M-Vizion Femoral Revision System (K201471, K191816 and K170690).

The M-VIZION Monobloc Stem is a monobloc cementless stem intended to be used for hip arthroplasty, in primary or revision surgeries. It shows a fluted tapered distal portion made of forged Ti-6Al-7Nb alloy according to ISO 5832-11 Second Edition 2014-09-15: Implants for Surgery – Metallic Materials – Part 11: Wrought Titanium 6– Aluminium 7-Niobium Alloy coated with a titanium coating, TiGrowth®-C (Medacta commercial name: Mectagrip); a proximal portion coated with Titanium Ti ASTM F 1580 and it is sandblasted distally.

The available size are:

- Length L190 mm ø12-26 mm STD/LAT;
- Length L240 mm ø12-26 mm STD/LAT;
- Length L290 mm ø12-26 mm STD/LAT.

The two versions STD/LAT have the following geometrical details:

- STD: CCD angle 132°, offset 37 mm;
- LAT: CCD angle 132°, offset 43 mm.

The M-VIZION Monobloc Stem is a range extension of the M-VIZION Modular Stem, from which it leverages most of the geometrical features such as the stem taper angle, the flutes design, the shape of the neck and proximal portion, and the Ti coating. Differently from the M-VIZION Monobloc Stem, the M- VIZION Modular Stem includes also a Locking Screw to fix the two parts.

The M-VIZION Monobloc Stems are substantially equivalent to Medacta primary predicate M-Vizion Femoral Revision System (K201471, K191816 and K170690) and to the secondary competitor predicate device Zimmer Biomet, Wagner SL Revision Stem (K953689, K043356).

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 Monobloc implants and the predicate devices share the following characteristics:

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

The M-VIZION Monobloc implants differ from the primary predicate devices as follow:

- it is monobloc
- no locking screw to fix the two components.

Discussion

Medacta International SA has not made any change to the indication for use, 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 Monobloc implants to the identified predicate devices.

The only differences between the subject and the primary predicate devices is the fact that now the stem is a monobloc cementless stem and for this reason no locking screw is required to fix the two components. These differences don'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 evaluation provided for Medacta's predicate device M-Vizion Femoral Revision System (K201471, K191816 and K170690) for the same materials support the biological safety of the M-Vizion Monobloc 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*

- Performance Tests
  - Range of motion (ROM): EN ISO 21535:2009 Non-Active Surgical Implants — Joint Replacement Implants — Specific Requirements For Hip-Joint Replacement Implants;
  - M-Vizion – neck worst case (FEM): ASTM F2996-13 Standard Practice for Finite Element Analysis of Non-Modular Metallic Orthopaedic Hip Femoral Stems
  - M-Vizion – shaft worst case (FEM): ASTM F2996-13 Standard Practice for Finite Element Analysis of Non-Modular Metallic Orthopaedic Hip Femoral Stems

- *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 Monobloc implants are as safe and effective as the predicate devices. Therefore, it is concluded that the M-Vizion Monobloc implants are substantially equivalent to the predicate devices.