



April 29, 2020

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

Re: K191816

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: April 27, 2020

Received: April 28, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqui, MS  
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

## Indications for Use

510(k) Number (if known)

K191816

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.

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K191816

## 510(k) Summary

### I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International  
SA Date Prepared: Jul 3, 2019

### 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, 21CFR 888.3390
Device Classification	II

### III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- M-Vizion Femoral Revision System, K170690, Medacta International SA

Secondary Predicate:

- Revision Femoral Stem, K151739, Limacoporate S.p.A.

### IV. Device Description

The M-Vizion Femoral Revision System 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 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 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 Extension devices are substantially equivalent to Medacta primary predicate M-Vizion Femoral Revision System (K170690) and to the secondary competitor predicate device Limacoporate S.p.A. Revision Femoral Stem (K151739).

## **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 and the predicate devices share the following characteristics:

- Indications for Use
- Materials
- Design
- Sterility
- Coating
- Device Usage

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

- Sizes
- Lengths
- Diameters

### *Discussion*

As seen above, the M-Vizion Femoral Revision System Extension implants are substantially equivalent to the predicate devices in terms of design; materials; coating; device usage; sterility; and indication for use.

The only difference between the subject and predicate devices are the new Proximal Body diameters and Distal Stem diameters and lengths (bigger and longer). These differences don't introduce any worst case condition 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, (K170690) for the same materials, support the biological safety of the M-Vizion Femoral Revision System Extension devices.

## **VII. Performance Data**

- Engineering Rationale

A comparative analysis of the subject devices to the identified predicate devices was performed to determine if the new sizes introduced created any new worst-case product size. It was determined that the subject stems are substantially equivalent to the previously cleared stems in terms of mechanical strength as new Proximal Body sizes keep the same geometry of the neck and head conical connection of the current  $\varnothing 20$  mm (Primary predicate K170690) and differ only for the cylindrical body external diameter and length. Considering the new Distal Stem sizes, they only differ from the predicate devices in regards to the diameters and/or length. As the additional sizes do not represent a worst case scenario the any of the mechanical characteristic tested for the already cleared predicate devices, no additional mechanical testing or design validation was undertaken.

The predicate M-Vizion Femoral Revision System devices (cleared under K170690) were tested using the worst-case device for each of the following tests:

### 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.
- o 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;
- o 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
- o 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.

#### Non-Clinical Studies

- No clinical studies were conducted.

The subject devices do not represent a new worst case when compared to the previously cleared devices (K170690) [see section **17.0 Performance Testing - Bench**].

The data and information provided in K170690 supports the conclusion that the M-Vizion Femoral Revision System Extension devices are safe and effective and conform to applicable standards and FDA guidance.

### **VIII. Conclusion**

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