March 2, 2021

Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 83118

Re: K210010
Trade/Device Name: GMK Revision & Hinge Extension - TiNbN Coating
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, JWH
Dated: December 30, 2020
Received: January 4, 2021

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,

Ting Song, Ph.D., R.A.C.
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)*
K210010

Device Name
GMK Revision Extension - TiNbN Coating

Indications for Use *(Describe)*
The Evolis/GMK knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.
This knee replacement system is indicated in the following cases:
•Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
•Avascular necrosis of femoral condyle.
•Post traumatic loss of joint configuration.
•Primary implantation failure.
Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.
The screwed tibial augments are for screwed fixation to the tibial baseplate.
In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components. In case a GMK Revision tibial tray is used, an extension stem must be implanted

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.

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)*
K210010

Device Name
GMK Hinge Extension - TiNbN Coating

Indications for Use *(Describe)*
The GMK® HINGE knee prosthesis is designed for cemented use in total knee arthroplasty when the preoperative diagnosis of the joint determines that the bone and stability situation require the implantation of a constrained prosthesis.
The GMK® HINGE knee system is indicated in the following cases:
• Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis associated with bone loss and/or severe joint instability
• Considerable loss of function of the knee joint
• High-grade joint destruction requiring additional stabilization with stems and reconstruction of bone defects with metal augmentation
• Failure of a primary prosthesis (e.g. infection, loosening)
• Former revision arthroplasty
• Post traumatic loss of joint configuration
• Avascular necrosis of femoral condyle.
Tibial augmentation are to be screwed to the tibial baseplate with both the two provided fixing screws.
When a GMK® HINGE implant is used it is mandatory to implant both the femoral and tibial components with an extension stem.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: December 30, 2020
Date Revised: January 8, 2021

II. Device

Device Proprietary Name:	GMK Revision & Hinge Extension - TiNbN Coating
Common or Usual Name:	Total Knee Prosthesis
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Primary Product Code:	KRO
Secondary Product Code	JWH
Regulation Number:	21 CFR 888.3510 and 21 CFR 888.3560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- GMK Revision, K102437, Medacta International SA
- GMK Revision SC Liners, K103170, Medacta International SA
- GMK-Revision Extension, K123721, Medacta International SA
- GMK Hinge, K130299, Medacta International SA
- GMK Revision Femoral Distal Augmentations, K163311, Medacta International SA
- GMK Hinge and GMK Revision, K172347, Medacta International SA
- GMK Total Knee System – TiNbN Coating, K202684, Medacta International SA

IV. Device Description

The GMK Revision & Hinge Extension - TiNbN Coating is a Medacta GMK line extension to provide a larger product offering. The subject devices are designed for cemented use in total knee arthroplasty procedures. The GMK Revision & Hinge Extension - TiNbN Coating includes the following implants:

- GMK Revision Femoral Component TiNbN coated, Standard and Posterior Stabilized, Left and Right, Sizes from 1 to 6
- GMK Revision tibial tray TiNbN coated, Left and Right, Sizes from 1 to 6
- GMK Revision SC peg TiNbN coated, sizes from 10 to 26 mm
- GMK Hinge Femoral Component TiNbN coated, Left and Right, Sizes from 1 to 6
- GMK Hinge tibial tray TiNbN coated, Left and Right, Sizes from 1 to 6
- GMK Hinge post extension TiNbN coated, sizes from 10 to 26 mm
- Screwed tibial augmentations Ti6Al4V, from 0 to 6 for thicknesses 5 and 10 and sizes from 1 to 6 for thicknesses 15 and 20 mm
- Femoral posterior augmentations Ti6Al4V, sizes from 1 to 6 thicknesses 4, 5, 8, and 10 mm
- Femoral distal augmentations Ti6Al4V, sizes from 1 to 6 thicknesses 4, 8, 12, 16 and 20 mm

The GMK Revision & Hinge - TiNbN Coating implants, both femoral components and Tibial trays, are manufactured from cobalt-chromium-molybdenum alloy (Co-Cr-Mo) according to ISO 5832-4:2014 Implants for Surgery - Metallic Materials-Part 4: Cobalt-Chromium-Molybdenum Casting Alloy with Titanium Niobium Nitride (TiNbN) coating.
The external and internal bushes, inside the GMK Hinge – TiNbN Coating femoral component, are manufactured from Type 1 Ultra High Molecular Weight Polyethylene (UHMWPE) according to ISO 5834-2:2019 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene -Part 2: Moulded Forms.
The GMK Revision SC peg & Hinge post extension, as well as the GMK hinge post and internal pivot inside the GMK Hinge – TiNbN Coating femoral component, are manufactured from cobalt-chromium-molybdenum alloy (Co-Cr-Mo) according to ISO 5832-12:2019 Implants for Surgery - Metallic Materials-Part 12: Wrought cobalt-chromium-molybdenum Alloy with Titanium Niobium Nitride (TiNbN) coating.
The GMK Revision & Hinge augmentations, both tibial and femoral, are manufactured from Ti6Al4V per ISO 5832-3:2016 Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.

V. Indications for Use

- GMK Revision
  The Evolis/GMK knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.
  This knee replacement system is indicated in the following cases:
  - Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
  - Avascular necrosis of femoral condyle.

- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.
The screwed tibial augments are for screwed fixation to the tibial baseplate.
In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components. In case a GMK Revision tibial tray is used, an extension stem must be implanted.

- GMK Hinge

  The GMK® HINGE knee prosthesis is designed for cemented use in total knee arthroplasty when the preoperative diagnosis of the joint determines that the bone and stability situation require the implantation of a constrained prosthesis.
  The GMK® HINGE knee system is indicated in the following cases:
  - Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis associated with bone loss and/or severe joint instability
  - Considerable loss of function of the knee joint
  - High-grade joint destruction requiring additional stabilization with stems and reconstruction of bone defects with metal augmentation
  - Failure of a primary prosthesis (e.g. infection, loosening)
  - Former revision arthroplasty
  - Post traumatic loss of joint configuration
  - Avascular necrosis of femoral condyle.

  Tibial augmentation are to be screwed to the tibial baseplate with both the two provided fixing screws.
  When a GMK® HINGE implant is used it is mandatory to implant both the femoral and tibial components with an extension stem.

VI. Comparison of Technological Characteristics

The GMK Revision & Hinge Extension - TiNbN Coating and the predicate devices (K102437, K103170, K123721, K130299, K163311, K172347) share the following characteristics:

- indications for use;
- sizes;
- shape, design and dimensions (except for femoral posterior augmentation screw);
- fixation to the body and connections;
- substrate material (except for tibial and femoral augmentations);
- device usage;
- sterility;
- shelf life; and
- packaging.

The GMK Revision & Hinge Extension - TiNbN Coating differs from the predicate devices (K102437, K103170, K123721, K130299, K163311, K172347) in relation to:

- femoral posterior augmentations additional thicknesses;
- femoral posterior augmentation connection screw dimension;
- coating; and
- tibial and femoral augmentations material.

VII. Performance Data

Based on the risk analysis, testing was conducted according to written protocols. The following tests are being provided in support of a substantial equivalence determination:

Non-Clinical Studies:

- PERFORMANCE TESTING
    - TiNbN coated Femoral Components Wear Behavior
    - Evaluation of modular tapered connection according to Medacta Test Protocol IL 07.09.517, Medacta Test Report A.2 and Endolab Test Report 167.181121.20.87 Rev.0
    - Femoral Modular Connection (Femoral Components + Femoral Distal and Posterior Augmentation)
    - TiNbN Coating Excessive Ions Release
    - TiNbN coated Femoral Component Mechanical Performances
    - TiNbN coated Tibial Trays Mechanical Performances
    - TiNbN coated Tibial Trays Connection with the insert
    - Tibial Tray Modular Connection (Tibial Tray + Offset + Extension Stem)
    - Tibial Modular Connection (Revision Tibial Tray + Tibial Augmentation)
    - GMK Revision TiNbN coated SC Peg Mechanical Performances
    - GMK Hinge TiNbN coated Post Extension Mechanical Performances
    - Ti6Al4V Femoral Augmentations Validation
    - Posterior Wedge Screw Design Validation Report according to Test Protocol IL 07.09.566
    - Ti6Al4V Tibial Augmentation Validation

- PYROGENICITY
    - Bacterial Endotoxin Test (LAL test) was conducted 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

- BIOCOMPATIBILITY assessment

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

Based on the above information, the GMK Revision & Hinge Extension - TiNbN Coating implants can be considered substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The GMK Revision & Hinge Extension - TiNbN Coating implants are as safe and effective as the predicate devices (K102437, K103170, K123721, K130299, K163311, K172347 and K202684).