December 11, 2020

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

Re: K202684
Trade/Device Name: GMK Total Knee System - TiNbN Coating
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 15, 2020
Received: September 15, 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,

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)*

K202684

Device Name
GMK Total Knee System - TiNbN Coating

Indications for Use *(Describe)*

The GMK Total Knee System 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.

GMK Sphere can be implanted using a kinematic alignment approach. When a kinematic alignment approach is utilized, 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.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus, or flexion deformities.

Cemented tibial wedges 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 the case of a semi-constrained liner is being used, an extension stem must be implanted both on the tibial and on the femoral components. In the case a GMK Revision tibial tray is being 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.

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: September 11, 2020

II. Device

Device Proprietary Name:	GMK Total Knee System - TiNbN Coating
Common or Usual Name:	Total Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Primary Product Code:	JWH
Regulation Number:	21 CFR 888.3560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- GMK Total Knee System, K090988, Medacta International SA
- GMK-Line Extension, K120790, Medacta International SA (also referred to as the GMK Total Knee System)
- GMK Sphere, K121416, Medacta International SA (also referred to as the GMK Total Knee System)
- GMK Narrow, K122232, Medacta International SA (also referred to as the GMK Total Knee System)
- GMK Sphere Extensions, K140826, Medacta International SA (also referred to as the GMK Total Knee System)
- GMK Extension, K142069, Medacta International SA (also referred to as the GMK Total Knee System)
- LINK® Endo-Model® Knee System with PorEx® (TiNbN) Coating, K152431, Waldemar Link GmbH & Company KG

IV. Device Description

The GMK Total Knee System - TiNbN Coating is a line extension to the GMK Total Knee System to provide a larger product offering. The subject devices are marketed as individually packaged femoral and tibial components, designed for cemented use in total knee arthroplasty procedures where there is evidence of sufficient sound bone to seat and support for the implants. GMK Total Knee System - TiNbN Coating includes the following implants:

- GMK Femoral Component, Standard and Posterior Stabilized, Left and Right, Sizes from 0 to 7
- GMK Femoral Component Narrow, Standard and Posterior Stabilized, Left and Right, Sizes from 1 to 7
- GMK-Sphere Femoral Component, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ (intermediate sizes)
- Tibial tray fixed cemented, Left and Right, Sizes from 1 to 6 plus 4 intermediate sizes.

The GMK Total Knee System - TiNbN Coating implants, both Femoral Components and Tibial Tray, 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 GMK Total Knee System - TiNbN Coating: Fixed Tibial Tray Plug is manufactured from Type 1 Ultra High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-2: 2019 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene -Part 2: Moulded Forms.

V. Indications for Use

The GMK Total Knee System 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.

GMK Sphere can be implanted using a kinematic alignment approach. When a kinematic alignment approach is utilized, 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.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus, or flexion deformities.

Cemented tibial wedges 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 the case of a semi-constrained liner is being used, an extension stem must be implanted both on the tibial and on the femoral components. In the case a GMK Revision tibial tray is being used, an extension stem must be implanted.

VI. Comparison of Technological Characteristics

The GMK Total Knee System - TiNbN Coating and the predicate devices GMK Total Knee System (K090988, K120790, K121416, K122232, K140826, K142069) share the following characteristics:

- indication for use
- design;
- fixation
- substrate material;
- device usage;
- sterility;
- shelf life; and
- packaging.

The GMK Total Knee System - TiNbN Coating differs from the predicate devices GMK Total Knee System (K090988, K120790, K121416, K122232, K140826, K142069) in relation to the coating only as the subject devices have a TiNbN coating while the predicate devices have no coating.

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
  - Evaluation of modular tapered connection according to Medacta Test Protocol IL 07.09.517 rev.0 and Medacta Test Report A.2, and Endolab Test Report 167.181121.20.87 Rev.0
  - Wear test 3 Mode according to Medacta Test Protocol IL 07.09.513 Rev. 2 and Medacta Test Report A.3 and Element Test Reports 00812-010290-1 and 00812-010290-3
  - Coating characterization according to ISO 11885
  - The following performance tests were previously conducted on the predicate devices and reviewed as part of the GMK Total Knee System submissions K090988, K120790, K121416, K122232, K140826 and K142069:
    - mechanical resistance of the femoral component under physiological static and dynamic loads;
    - mechanical resistance of the tibial tray under physiological static and dynamic loads;
    - connection of the tibial tray with the tibial insert.

- 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
  - Biocompatibility assessment and related testing as per *ISO 10993 series and FDA Biocompatibility Guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

Based on the above information, the GMK Total Knee System - 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 Total Knee System - TiNbN Coating implants are as safe and effective as the predicate devices, GMK Total Knee System (K090988, K120790, K121416, K122232, K140826, K142069).