January 20, 2023

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

Re: K223548
Trade/Device Name: GMK Sphere & GMK SpheriKA Cementless
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: November 23, 2022
Received: November 25, 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,

Ting Song -S

Ting Song, Ph.D.
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)*
K223548

Device Name
GMK Sphere & GMK SpheriKA Cementless

Indications for Use *(Describe)*

The GMK knee cemented prosthesis is designed for cemented application in total knee arthroplasty if there is evidence of sufficient sound bone to seat and support the components.
The use of the cementless GMK femur is limited to cases in which the surgeon considers the bone quality to be sufficient for cementless applications.
The GMK 3D Metal Tibial Baseplate is indicated for cementless or cemented application 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
• Collagen disorders, and avascular necrosis of the 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 or GMK Sphere Revision tibial tray is used, an extension stem must be implanted.
It is not possible to implant tibial wedges and extension stems with the GMK 3D Metal Tibial Baseplate.

Limitations for use for GMK Sphere/GMK SpheriKA used with kinematic alignment
GMK Sphere and GMK SpheriKA can be implanted in kinematic alignment. In this case, this knee replacement system is indicated for:
• 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.

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, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: November 23, 2022
Date Revised: January 13, 2023

II. Device

Device Proprietary Name:	GMK Sphere & GMK SpheriKA Cementless
Common or Usual Name:	Total Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Primary Product Code:	MBH
Regulation Number:	21 CFR 888.3565
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary predicate device

- LEGION Porous Plus HA Primary Femoral Components, K091543, Simth & Nephew, Inc.

Secondary predicate devices

- GMK Sphere, K121416, 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 SpheriKA, K211004, Medacta International SA
- Vanguard Complete Knee System, K113550, Biomet Manufacturing Corp.

Reference devices

- Versafit Cup Double Mobility Cementless Acetabular shells, K083116, Medacta International SA

- Evolis Total Knee System, Cementless femur porous Ti coated, K081023, Medacta International SA.

IV. Device Description

The GMK Sphere & GMK SpheriKA Cementless is a line extension to the GMK Total Knee System and includes the following devices:

- GMK Sphere Cementless Femoral Components, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ (intermediate sizes);
- GMK SpheriKA Cementless Femoral Components, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ (intermediate sizes);
- GMK SpheriKA ST Cementless Femoral Components, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ (intermediate sizes).

The subject devices are marketed as individually packaged femoral components, designed for cementless use in total knee arthroplasty procedures where the surgeon considers the bone quality to be sufficient for cementless applications.

The GMK Sphere & GMK SpheriKA Cementless implants 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 double-layer coating composed of Titanium plasma spray according to ISO 13179-1 *Implants for surgery-- Plasma-sprayed unalloyed titanium coatings on metallic surgical implants -- Part 1: General requirements* and Hydroxyapatite according to ISO 13779-2 *Implants for surgery - Hydroxyapatite - Part 2: Thermally sprayed coatings of hydroxyapatite* on the internal surface pockets.

V. Indications for Use

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components. In case a GMK Revision or GMK Sphere Revision tibial tray is used, an extension stem must be implanted.
It is not possible to implant tibial wedges and extension stems with the GMK 3D Metal Tibial Baseplate.

Limitations for use for GMK Sphere/GMK SpheriKA used with kinematic alignment
GMK Sphere and GMK SpheriKA can be implanted in kinematic alignment. In this case, this knee replacement system is indicated for:

- 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.

VI. Comparison of Technological Characteristics

The subject GMK Sphere & GMK SpheriKA Cementless and the predicate devices (K121416, K140826, K211004) share the following characteristics:

- sizes and design;
- substrate material;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The subject GMK Sphere & GMK SpheriKA Cementless differ from the predicate devices (K121416, K140826, K211004) with respect to:

- fixation; and
- coating.

The presence of a double-layer coating of the subject devices with respect to the predicate is justified by the different fixation method: cementless for the subject devices and cemented for the predicate (K121416, K140826, K211004). This difference does not raise any new issue related to subject devices' safety and effectiveness since it is shared with the primary predicate LEGION Porous Plus HA Primary Femoral Components (K091543) and with the additional predicate Vanguard Complete Knee System (K113550) and is supported by performance data.

VII. Performance Data

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

<u>Non-Clinical Studies:</u>

- PERFORMANCE TESTING

- GMK Sphere porous coated femoral components mechanical properties
- GMK SpheriKA porous coated femoral components mechanical properties
- Scanning Electron Microscopy analysis of Medacta GMK Sphere femoral components
- Cross Sectioned Area of the coated implant surfaces of the Medacta GMK Sphere femoral component
- XRD analyses comparing the coating features deposed in the Medacta GMK Sphere femoral component and on planar samples made of CoCr

- 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 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"*

- SHELF-LIFE evaluation

Clinical Studies

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the GMK Sphere & GMK SpheriKA Cementless 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.