July 29, 2021

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

Re: K211664
Trade/Device Name: GMK Sphere Revision
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: May 28, 2021
Received: June 1, 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,

For 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211664

Device Name
GMK Sphere Revision

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 or GMK Sphere Revision tibial tray is used, an extension stem must be implanted.

Type of Use *(Select one or both, as applicable)*

[X] 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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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: May 27, 2021
Date Revised: July 28, 2021

II. Device

Device Proprietary Name:	GMK Sphere Revision
Common or Usual Name:	Total Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semiconstrained 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:
Primary predicate device

- GMK Sphere, K121416, Medacta International SA

Secondary predicate devices

- GMK Revision, K102437, Medacta International SA
- GMK Revision Extension, K123721, Medacta International SA
- GMK Total Knee System – TiNbN Coating, K202684, Medacta International SA
- GMK Revision & Hinge – TiNbN Coating, K210010, Medacta International SA

IV. Device Description

The GMK Sphere Revision 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 Sphere Revision system includes:

- Femoral components, left and right, sizes from 2 to 8, with or without TiNbN coating;
- Tibial trays, left and right, sizes T3I4 and T4I3, with or without TiNbN coating;
- Distal wedges, 4 sizes (2, 3-4, 5-6, 7-8) with thicknesses 4, 8, 12, 16 and 20 mm;
- Posterior wedges, 6 sizes (2, 3-4, 5, 6, 7, 8) with thicknesses 4, 8 and 12 mm;
- Offset connectors from 2 to 5 mm.

The GMK Sphere Revision implants, both femoral components and tibial trays, are manufactured from cobalt-chromium-molybdenum alloy (Co-Cr-Mo) according to ISO 5832-4 and they are available with or without Titanium Niobium Nitride (TiNbN) coating.
The GMK Sphere Revision wedges and offset connectors, are manufactured from Ti6Al4V per ISO 5832-3.

V. Indications for Use

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 or GMK Sphere Revision tibial tray is used, an extension stem must be implanted.

VI. Comparison of Technological Characteristics

The GMK Sphere Revision implants and the predicate devices share the following characteristics:

- indications for use;
- shape and design (except for ML dimension and posterior condyle height of the femoral components and tibial trays holes);
- fixation;
- materials;
- coating (when applicable);
- biocompatibility;
- device usage;
- sterility; and
- packaging.

The GMK Sphere Revision implants differ from the predicate devices as follow:

- sizes;
- ML dimension and posterior condyle height of the femoral components; and

- tibial trays holes.

Discussion
Medacta International SA has not made any change to the indications for use, general design and shape, materials and coating, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.
Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the GMK Sphere Revision implants to the identified predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - GMK Sphere Revision – ROM and mobility of the articulating surface (per ISO 21536 and ASTM F2083)
  - GMK Sphere Revision – Dynamic Endurance test of the Posterior Femoral Condyle (per ISO 7207-1:07, ISO 7207-2:11, ISO 5832-4:14, ASTM F 1814-15, ASTM F 2083-12, ASTM F 1800-19, ASTM F 3161-16)
  - GMK Sphere Revision – Dynamic Endurance test in combination with Extension Stem (per ASTM F 1814-15, ASTM F 897-02, ASTM F 1800-19, ASTM F F2009-20, ISO 7207-1:07, ISO7207-2:11, ISO 5832-4:14, ISO 5832-3:16, ISO 14243-1:09, ISO 5834-2:19)
  - GMK Sphere Revision – Tibial augmentation screwed connection (per PI-53: 2010-11 and ASTM F2009-20)
  - GMK Sphere Revision femoral components Wear behavior (per ISO 14243-1)
  - TiNbN Coating Excessive Ions Release (per ISO 21534, ISO 14577, ISO 5832-2, ISO 14243-1, EN ISO 10993, EN ISO 10993-1, ISO 10993-18, and EN ISO 10993-6)

- *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.

- *BIOCOMBATIBILITY evaluation*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the GMK Sphere Revision implants are substantially equivalent to the predicate devices.