May 13, 2021

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

Re: K211004
Trade/Device Name: GMK-SPHERE Spherika Femurs and Tibial Trays plus
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: April 1, 2021
Received: April 2, 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)*

K211004

Device Name
GMK-SPHERE Spherika Femurs and Tibial Trays plus

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.

GMK Sphere/Spherika 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.

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.

3.0 510(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: April 1, 2021

II. Device

Device Proprietary Name:	GMK-SPHERE Spherika Femurs and Tibial Trays plus
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 device:

- Medacta International SA, GMK Sphere K121416

Reference predicates:

- Medacta International SA, GMK Sphere Extension, K140826
- Medacta International SA, GMK Sphere Extension, K162035
- Medacta International SA, GMK Sphere - Kinematic Alignment, K173890
- Medacta International SA, GMK Sphere E-Cross K202022
- Medacta International SA, GMK Total Knee System - TiNbN Coating, K202684
- Medacta International SA, GMK Total Knee System, K090988
- Medacta International SA, GMK Line Extension K120790
- Medacta International SA, GMK Narrow K122232
- Medacta International SA, GMK Extension K142069

IV. Device Description

The purpose of this submission is to notify the FDA of the GMK SPHERE range Extension, that includes GMK Spherika Femurs and GMK Fixed Tibial Trays Plus.

Subject devices are sterile implantable devices designed for tricompartmental replacement of the natural knee joint.

The subject devices are marketed as individually packaged femoral and tibial components, designed for cemented use in total knee arthroplasty procedures.

GMK Spherika femoral component is an implantable device intended to be used in case of total knee arthroplasty to replace the femoral articular surfaces of the knee joint.
GMK Spherika femoral component can be used in Kinematic Alignment surgical technique.
The Kinematic Alignment surgical technique was already cleared in K173890.

GMK Tibial Trays Plus are a range extension of the GMK Tibial trays already cleared, in details they are fixed intermediate sizes of the tibia trays.

The subject devices are a line extension to Medacta previously cleared implants: GMK Sphere (K121416), GMK Sphere Extension (K140826), GMK Knee Prosthesis- GMK Sphere Tibial Insert Flex (K162035), GMK Sphere - Kinematic Alignment (K173890), GMK Sphere CR Tibial Inserts (K181635), GMK Sphere E-Cross (K202022), GMK Total Knee System-TiNbN Coating (K202684), Medacta International SA, GMK Total Knee System (K090988), GMK Line Extension (K120790), GMK Narrow K122232, MK Extension (K142069) and

The subject devices are manufactured with the same materials of the previous cleared femurs and tibial trays.

The submission includes the following implants:

- GMK Spherika Femoral Component Cemented, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ made in Co-Cr-Mo (ISO 5832-4)
- GMK Spherika Femoral Component Cemented, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ made in Co-Cr-Mo (ISO 5832-4) and TiNbN Coated
- GMK Spherika Femoral Component Anatomical, Cemented, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ made in Co-Cr-Mo (ISO 5832-4)
- GMK Spherika Femoral Component Anatomical, Left and Right, Sizes from 1 to 7 and from 1+ to 6+ made in Co-Cr-Mo (ISO 5832-4) and TiNbN Coated
- Tibial tray fixed cemented, Left and Right, Sizes from 1+ to 5+ plus 4 intermediate sizes made in Co-Cr-Mo (ISO 5832-4)
- Tibial tray fixed cemented, Left and Right, Sizes from 1+ to 5+ plus 4 intermediate sizes made in Co-Cr-Mo (ISO 5832-4) and TiNbN Coated

The subject devices, 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.

In regards to the Femurs and Tibial Trays TiNbN Coating, they 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.

Like the predicate tibial trays devices, the tibial trays plus subject of this submission have a Fixed Tibial Tray Plug that 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.

The subject device also includes the utilization of the GMK Sphere E-cross tibial insert FLEX, already cleared (K202022) in case of retention of an efficient posterior cruciate ligament in the Kinematic Alignment configuration.

The Kinematic Alignment surgical technique was already cleared in K173890.

In this case there are no new implants or instruments, GMK Sphere E-cross tibial insert FLEX, already cleared (K202022).

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 tibial tray is used, an extension stem must be implanted.

GMK Sphere/Spherika 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.

VI. Comparison of Technological Characteristics

- *GMK Spherika Standard femoral component*

GMK Spherika Standard Femoral Components and the Medacta predicate devices GMK SPHERE (K121416, K140826, K173890, K202684, K090988, K120790 and K142069) share the following characteristics:

- Sizes;
- Indication for use;
- Material;
- Packaging,
- Device Usage;
- Biocompatibility
- Shelf Life; and
- Sterilization Method.

GMK Spherika Standard Femoral Components and the Medacta predicate devices are technologically different from the predicate device as follows:

- anterior trochlea orientation

- *GMK Fixed Tibial Trays Plus*

Fixed Tibial Trays Plus implants and the predicate devices (K121416, K140826, K173890, K202684, K090988, K120790 and K142069) share the following characteristics:

- Shape;
- Instruction for use;
- Packaging
- Device Usage;
- Biocompatibility;
- Shelf Life; and
- Sterilization Method.

Fixed Tibial Trays Plus implants are technologically different from the predicate device as follows:

- Sizes (adding intermediate sizes)

Regarding the utilization of the GMK Sphere E-Cross tibial insert FLEX, already cleared (K202022) in case of retention of an efficient posterior cruciate ligament in Kinematic Alignment configuration there are no differences in the fundamental scientific technology. This is an additional surgical technique for use with the the GMK Sphere E-cross tibial insert FLEX.

VII. Performance Data

A review of the mechanical data on the subject and predicate devices indicates that the subject devices are substantially equivalent to devices currently cleared for use and does not alter the intended surgical outcomes. The purpose of this submission is to introduce a line extension of the already cleared GMK-SPHERE system already cleared. The new devices design introduction was evaluated by risk analysis to identify any new risks associated. Based on the risk analysis, additional tests have been performed in order to demonstrate that the subject devices are substantially equivalent to the identified predicate devices.

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- PERFORMANCE TESTING
    - GMK Spherika Dynamic Endurance test of the Posterior Femoral Condyle, Test Report
    - Rationale of equivalence with predicate devices constraints of GMK Spherika Femoral Component in combination with GMK Sphere Tibial Insert, Test Report A.2
    - Rationale of equivalence with predicate device contact areas and pressures of GMK Spherika femoral component in combination with GMK Sphere Tibial Insert, Test Report A.3
    - GMK Spherika Femoral Component in combination with GMK Sphere tibial insert range of motion of the articulating Surfaces, Test Report A.4
    - Rationale of equivalence with predicated device constraints of GMK Resurfacing and Moto Patella Articulating with GMK Spherika Femoral component and GMK Spherika anatomical femoral component, Test Report A.5
    - Rationale of Equivalence with predicate device GMK Resurfacing and Moto patella Articulating on GMK Spherika Femoral Component and GMK-Spherika Anatomical Femoral Component, Test Report A.6

- GMK Spherika Femoral Component, Design Validation Report Nr.1
- GMK Spherika Optimization of Bone Coverage of the GMK Sphere Femoral Component Kinematically Aligned, Test Report A8
- Validation test for GMK Sphere E-Cross tibial insert FLEX indication as CR option

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, K142069, K173890, K202684 :

- 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.
- Evaluation of modular tapered connection
- Wear test
- Coating characterization according to ISO 11885

- 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

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

Based on the above information, the subject devices are 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 subject implants are substantially equivalent to the predicate devices.