August 23, 2018

Medacta International SA
% Elizabeth Rose
Manager, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K173890
Trade/Device Name: GMK Sphere - Kinematic Alignment
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: December 21, 2017
Received: December 21, 2017

Dear Elizabeth Rose:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.08.23 17:12:07 -04'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K173890

Device Name
GMK Sphere - Kinematic Alignment

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.

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.

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.

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 Affairs Manager
Date Prepared: December 21, 2017
Date Revised: July 3, 2018

II. Device

Device Proprietary Name:	GMK Sphere – Kinematic Alignment
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	2

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices:

- GMK Sphere, K121416, Medacta International SA
- GMK Sphere Extension, K140826, Medacta International SA
- GMK Sphere, K162035, Medacta International SA

Additional Predicate Devices:

- Zimmer Persona Personalized Knee System, K172524, Zimmer, Inc.

IV. Device Description

The purpose of this submission is to gain clearance for the GMK Sphere – Kinematic Alignment surgical technique and the technique specific instruments. The proposed kinematic alignment technique is an alternative alignment strategy to the traditional mechanical alignment used for total knee arthroplasty. The purpose of the kinematic alignment technique is to restore normal knee function by aligning the distal and posterior femoral joint lines of the tibial component to those of the normal or pre-arthritic state.

The GMK Sphere – Kinematic Alignment surgical technique will be used with the following components of the GMK Sphere System cleared under K121416, K140826, and K162035:

- Tibial Insert Fixed Flex: Left and Right, Sizes 1 - 6, 10 - 20 mm (including intermediate sizes 11 mm and 12 mm), UHMWPE Type 1, Fixation Screw: Ti6Al4V;
- Femoral Component Left and Right, Sizes 1 - 7, Co-Cr-Mo;
- Femoral Component Left and Right, Sizes 1+ - 6+ (intermediate sizes), Co-Cr-Mo;
- Tibial Tray Fixed Cemented Left and Right, 4 intermediate sizes, Co-Cr-Mo;
- Tibial Insert Fixed Flex, Left and Right, Sizes 1 - 6, 10 mm - 20 mm, UHMWPE Type 1, Ti6Al4V;
- Tibial Insert Fixed Flex, Left and Right, Sizes 1 - 6, 11 mm and 13 mm, UHMWPE Type 1, Ti6Al4V; and
- instrumentation.

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; and
- 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; and
- moderate valgus, varus, or flexion deformities.

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.

VI. Comparison of Technological Characteristics

With the exception of the new instruments to be used with the kinematic alignment surgical technique, there are no differences in the fundamental scientific technology of the GMK Sphere – Kinematic Alignment. The safety and effectiveness of the surgical technique is adequately supported by the substantial equivalence information provided within this Premarket Notification.

The implants and instruments to be used with the GMK Sphere – Kinematic Alignment technique are exactly the same as the previously cleared GMK Sphere devices.

This submission introduces the kinematic alignment technique as an additional surgical technique for use with the GMK Sphere implants; this technique requires the use of more instrumentation than the previously cleared mechanical alignment surgical technique.

VII. Performance Data

As the subject devices are a line extension to the GMK Sphere family, verification activities, as identified through risk analysis, were conducted to written protocols with pre-defined acceptance criteria.

The following performance tests, conducted on the predicate devices, are being leveraged in support of this submission:

- mechanical resistance of the femoral component under physiological static and dynamic loads;
- wear behavior;
- range of motion;
- mechanical resistance of the tibial tray under physiological static and dynamic loads;
- sterilization validation;
- shelf life; and
- pyrogenicity.

Risks were identified based on the proposed surgical technique and testing was conducted to mitigate those risks. Based on the risk analysis, the following tests were conducted on the subject devices according to written protocols with acceptance criteria:

Non-Clinical Studies

- Performance Tests
  - range of motion (ROM);
  - expected loads;
  - level of constraints;
  - primary and secondary fixation; and
  - cadaveric workshop for validation of the surgical technique and the relative dedicated instruments set.

VIII. Conclusion

Based on the above information, the GMK Sphere – Kinematic Alignment 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 Sphere – Kinematic Alignment is as safe and effective as the predicate devices.

----------This space intentionally left blank----------