August 23, 2018

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

Re: K181635
Trade/Device Name: GMK Sphere CR Tibial Inserts
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: July 9, 2018
Received: July 10, 2018

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/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,

Peter G. Allen -S
2018.08.23 12:38:28 -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)*
K181635

Device Name
GMK Sphere Cruciate Retaining Tibial Inserts

Indications for Use *(Describe)*
The 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.

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.

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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Date Prepared: June 20, 2018

II. Device

Device Proprietary Name:	GMK Sphere CR Tibial Inserts
Common or Usual Name:	Tibial Inserts
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 Sphere – K121416, Medacta International SA;
- GMK Sphere Extension – K140826, Medacta International SA; and
- GMK Sphere Tibial Insert Flex – K162035, Medacta International SA.

IV. Device Description

The GMK Sphere CR Tibial Inserts are a line extension to the GMK Sphere Total Knee System and are comprised of the following products:

- Tibial insert fixed CR: Left and Right, Sizes 1-6, Thicknesses 10-11-12-13-14 mm, UHMWPE (ISO 5834-2) Type 1.

The purpose of this submission is to introduce a new GMK Sphere insert design that does not require Posterior Cruciate Ligament (PCL) release. The introduction of the subject items does not require additional instrumentation needed during the surgical procedure (with exception of the specific CR trial tibial inserts) and does not alter the intended use or outcomes.
The following components of the GMK Sphere have been cleared previously under K121416 and K140826 predicate device:

- Femoral Component Left and Right, Sizes 1-7 Co-Cr-Mo (ISO 5832-4 Third Edition 2014-09-15 Implants for Surgery – Metallic Materials – Part 4: Cobalt-Chromium-Molybdenum Casting Alloy);
- Femoral Component Left and Right, Sizes 1+ to 6+ (intermediate sizes) Co-Cr-Mo (ISO 5832-4 Third Edition 2014-09-15 Implants for Surgery – Metallic Materials – Part 4: Cobalt-Chromium-Molybdenum Casting Alloy);
- Tibial tray fixed cemented Left and Right, 4 intermediate sizes Co-Cr-Mo (ISO 5832-4 Third Edition 2014-09-15 Implants for Surgery – Metallic Materials – Part 4: Cobalt- Chromium-Molybdenum Casting Alloy);
- Tibial Insert Fixed Flex, Left and Right, Sizes 1-6, 10mm -20mm UHMWPE (ISO 5834 2:2011 Implants for Surgery – Ultra-High-Molecular-Weight Polyethylene – Part 2: Moulded Forms) Type 1, Ti6Al5V (ISO 5832-3:1996 Implants for Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy);
- Tibial Insert Fixed Flex, Left and Right, Sizes 1-6, 11mm and 13mm UHMWPE (ISO 5834-2:2011 Implants for Surgery – Ultra-High-Molecular-Weight Polyethylene – Part 2: Moulded Forms) Type 1, Ti6Al4V (ISO 5832-3:1996 Implants for Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy; and
- Instrumentation.

The following components of the GMK Sphere have been cleared previously under the Medacta GMK Total Knee System:

- Resurfacing patella Sizes 1-4 (K090988 and K113571);
- Tibial tray fixed cemented Left and Right, Sizes 1-6 (K090988); and
- Primary extension stem Ø 11mm/ L 65mm (K090988) and L 30mm (K133630).

V. Indications for Use

The 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.

VI. Comparison of Technological Characteristics

The GMK Sphere CR Tibial Insert and the predicate devices share the following characteristics:

- Indications for Use;
- Sizes;
- Materials;
- Packaging, with exception of the screw, not included for the subject devices. The use of the inlay screw became optional with K162035;
- Device Usage;
- Shelf Life; and
- Sterilization Method.

The GMK Sphere CR Tibial Insert is technologically different from the predicate devices as follows:

- Thickness is limited to 14 mm. Thicknesses 17 and 20mm are not available because implanting similar thicknesses requires a tibial resection too distal that doesn't allow retaining PCL ligament.
- Specific cruciate retaining design:
    1. reduced medial anterior lip, as a consequence of the reduced risk of femoral anterior dislocation due to the presence of the PCL
    2. reduced posterior congruency, thus being able to accommodate femoral posterior roll-back during flexion due to the presence of the PCL
    3. posterior opening for PCL, created to accommodate the ligament, avoiding impingement during flexo-extension motion. The posterior PCL medio-lateral opening lengths are the same as the already cleared GMK Primary CR inserts (K090988).

Biocompatibility testing conducted on the predicate devices for the same material supports the biological safety of the GMK Sphere CR Tibial Inserts. Additional testing was deemed unnecessary.

A review of the mechanical data indicates that the GMK Sphere CR Tibial Inserts are equivalent to devices currently cleared for use and are capable of withstanding expected in vivo loading without failure. The GMK Sphere CR was compared to the worst case predicate device in terms of fatigue, wear, and range of motion and it was determined that the GMK Sphere CR is not worst case.

VII. Performance Data

A review of the mechanical data on the subject and predicate devices indicates that the additional cruciate retaining insert is equivalent to devices currently cleared for use and does not alter the intended surgical outcomes. The purpose of this submission is to introduce a new GMK Sphere insert design that does not

require Posterior Cruciate Ligament (PCL) release. The introduction of the subject items does not require additional instrumentation needed during the surgical procedure, with exception of the specific CR trial tibial inserts. The new CR insert 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 new CR inserts are as safe as effective as the predicate devices.

The GMK Sphere CR was tested for the following compared to the predicate devices:

- Constraint measurements;
- Contact pressures and areas;
- Dynamic physiological loads; and
- Range of Motion.

VIII. Conclusion

The information provided above supports that the GMK Sphere CR Tibial Inserts are as safe and effective as the predicate devices. The main purpose of the submission is to introduce a new GMK Sphere insert design that does not require Posterior Cruciate Ligament (PCL) release. The addition of the new cruciate retaining insert design and the thickness limitation to 14 mm does not raise any new questions of safety and effectiveness. Therefore, it is concluded that the GMK Sphere CR Tibial Inserts are substantially equivalent to the predicate devices.

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