DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 6, 2017

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

Re: K162035
Trade/Device Name: GMK Sphere
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: February 9, 2017
Received: February 10, 2017

Dear Mrs. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162035

Device Name
GMK® Sphere

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: July 21, 2016
Date Revised: February 9, 2017

II. Device

Device Proprietary Name:	GMK® Sphere
Common or Usual Name:	Tibial Inserts
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulation Number:	21 CFR 888.3560
Product Code:	JWH
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

GMK Sphere – K121416, Medacta International SA
GMK Sphere Extension – K140826, Medacta International SA

IV. Device Description

The GMK Sphere Tibial Insert Flex is a line extension to the GMK Sphere Total Knee System and is comprised of the following products:

- Tibial Insert Fixed Flex: Left and Right, Sizes 1-6, 10-20mm (including intermediate sizes 11mm and 13mm) UHMWPE (ISO 5834-2)Type 1, Fixation Screw: Ti6Al5V (ISO 5232-3)

The purpose of this submission is to modify the surgical technique provided to surgeons to show that the GMK Sphere Tibial Insert Flex titanium screws' use as optional, instead of required. This technique modification 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
- Instrumentation

The following components of the GMK Sphere have been cleared previously under the Medacta GMK Total Knee System, K121416:

- Resurfacing patella Sizes 1-4 (K090988 and K113571)
- Tibial tray fixed cemented Left and Right, Sizes 1-6 (K090988)
- 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 Tibial Insert Flex and the predicate devices share the following characteristics:

- Indications for Use
- Materials
- Packaging
- Device Usage
- Shelf Life
- Sterilization Method

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

- Thickness sizes available
- Optional use of fixation screw in the Surgical Technique

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

A comparison of the subject and predicate devices is provided in the table below.

Technological comparison

	GMK Sphere Tibial Insert Flex Subject Device	**GMK Sphere Extension (K140826)**	**GMK Sphere (K121416)**
Material of Construction	UHMWPE (ISO 5834-2) with Titanium alloy Screw (ISO 5832-3)	Same	Same
Sterilization Method	Ethylene Oxide	Same	Same
Device Usage	Single Use	Same	Same
Sizes	6 sizes (1 to 6)	Same	Same
Thickness	7 levels of thickness (10, 11, 12, 13, 14, 17, 20mm)	Same	5 levels of thickness (10, 12, 14, 17, 20mm)
Shelf Life	5 years	Same	Same

Discussion
As seen above, the difference between the subject and predicate devices is that the subject device has additional thicknesses. The main purpose of the submission is to update the surgical technique to make the fixation screw included in the packaging of the GMK Sphere Tibial Insert Flex an optional feature for additional fixation, instead of being required for fixation.

The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the subject device is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

VII. Performance Data

A review of the mechanical data on the subject and predicate devices indicates that the modified use of the subject device, usage of fixation screw of GMK Sphere Tibial Insert Flex as optional instead of required, is equivalent to devices currently cleared for use and does not alter the intended surgical outcomes. The purpose of this submission is to update the surgical technique to show that the GMK Sphere Tibial Insert Flex does not require the fixation screws included in the packaging and that they are optional devices for additional fixation. The modification was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, static analysis combined with previous static and dynamic/fatigue test on the clipping system, the GMK Sphere Tibial Insert Flex remains safe and consistent for the intended use though the fixation screw is not used.

The following analyses were conducted or were leveraged to support the substantial equivalence of the subject devices:

- Static and Dynamic/Fatigue Test on Clipping System (K090988)
- Sterilization Validation
- Shelf Life
- Limulus Amebocyte Lysate (LAL) testing was evaluated to establish the device meets pyrogen limit specifications.

Medacta does not intend to make a claim of "non-pyrogenic" on the device labeling for the Femoral Distal Augmentations.

VIII. Conclusion

The information provided above supports that the GMK Sphere Tibial Insert Flex is as safe and effective as the predicate devices. The main purpose of the submission is to update the surgical technique to make the fixation screw included in the packaging of the GMK Sphere Tibial Insert Flex an optional feature for additional fixation, instead of being required for fixation. The change

to the surgical technique and addition of thicknesses available of the subject device as compared to the predicate devices, do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the GMK Sphere Tibial Insert Flex is substantially equivalent to the predicate devices.