JUL 15 2014

Medacta International

510(k) Summary

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Date Prepared: March 28, 2013

DEVICE INFORMATION

Trade/Proprietary Name: GMK Sphere Extension
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
21 CFR 888.3560
Class II
Product Code(s): JWH

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K121416	GMK Sphere	Medacta International	7/30/2012
K090988	GMK Total Knee System	Medacta International	7/10/2009

Product Description

The GMK Sphere Total Knee System allows for medial-pivot rotation of the knee joint. The GMK Sphere Extension is a line extension to the GMK Sphere Total Knee System and is comprised of the following implants:

- Femoral Component Left and Right, Sizes 1+ to 6+ (intermediate sizes)
  Co-Cr-Mo (ISO 5832-4)
- Tibial Insert Fixed Flex, Left and Right, Sizes 1-6, 11mm and 13mm (intermediate sizes)
  UHMWPE (ISO 5834 -2) Type 1, Ti6Al4V (ISO 5232-3)

The following components of the GMK Sphere have been previously cleared under the K121416 predicate device:

- Femoral Component Left and Right, Sizes 1-7
  Co-Cr-Mo (ISO 5832-4)
- Tibial tray fixed cemented Left and Right, 4 intermediate sizes
  Co-Cr-Mo (ISO 5832-4)
- Tibial Insert Fixed Flex and Congruent, Left and Right, Sizes 1-6, 10mm-20mm
  UHMWPE (ISO 5834 -2) Type 1, Ti6Al4V (ISO 5232-3)

The following components of the GMK Sphere have been previously cleared under the Medacta GMK Total Knee System, which is the primary predicate to K121416 GMK Sphere:

- Resurfacing patella Sizes 1-4 (K090988 and K113571)
- Tibial tray fixed cemented Left and Right, Sizes 1-6 (K090988)
- Primary extension stem Ø11mm / L 65 mm (K090988) and L 30mm (K133630)

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.

Comparison to Predicate Devices

The indications for use, design features and materials of the GMK Sphere Extension are substantially equivalent to those of the predicate devices. The substantial equivalence of the GMK Sphere Extension implants is supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

Performance Testing

The modification to the device system to include the addition of the GMK Sphere Extension was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The GMK Sphere Extension was compared to the worst case predicate device in terms of fatigue, wear, constraints, clipping system, and range of motion and it was determined that the GMK Sphere Extension is not worst case.

Conclusion:

Based on the above information, the GMK Sphere Extension can be considered as substantially equivalent to its predicate devices.

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

July 15, 2014

Medacta International
Mr. Adam Gross
Director of Regulatory, Quality and Compliance
1556 West Carroll Avenue
Chicago, Illinois 60607

Re: K140826
Trade/Device Name: GMK Sphere Extension
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class: Class II
Product Code: JWH
Dated: April 15, 2014
Received: April 16, 2014

Dear Mr. Gross:

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 yours,

Lori A. Wiggins

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140826

Device Name
GMK Sphere Extension

Indications for Use *(Describe)*
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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.
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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

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FORM FDA 3881 (1/14)