DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 21, 2016

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

Re: K163311
Trade/Device Name: GMK Revision-Femoral Distal Augmentation
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO, JWH
Dated: November 23, 2016
Received: November 23, 2016

Dear Ms. 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,

Lori A. Wiggins -S

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 below.

510(k) Number *(if known)*
K163311

Device Name
GMK Revision-Femoral Distal Augmentation

Indications for Use *(Describe)*
The GMK® Total Knee System 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.

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
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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)*

Device Name
GMK Revision- Femoral Distal Augmentation

Indications for Use *(Describe)*

The GMK HINGE knee prosthesis is designed for cemented use in total knee arthroplasty when the preoperative diagnosis of the joint determines that the bone and stability situation require the implantation of a constrained prosthesis.

The GMK HINGE knee system is indicated in the following cases:

· Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis associated with bone loss and/or severe joint instability
· Considerable loss of function of the knee joint
· High-grade joint destruction requiring additional stabilization with stems and reconstruction of bone defects with metal augmentation
· Failure of a primary prosthesis (e.g. infection, loosening)
· Former revision arthroplasty
· Post traumatic loss of joint configuration
· Avascular necrosis of femoral condyle.

Tibial augmentation are to be screwed to the tibial baseplate with both the two provided fixing screws.

When a GMK HINGE® implant is used it is mandatory to implant both the femoral and tibial components with an extension stem.

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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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: November 23, 2016

II. Device

Device Proprietary Name:	GMK Revision-Femoral Distal Augmentation
Common or Usual Name:	Total knee prosthesis
Classification Name:	Prosthesis knee, Femorotibial, Constrained Cemented, Metal/Polymer Knee joint, patellofemorotibial polymer/metal/polymer semi constrained cemented prosthesis
Regulation Number:	21 CFR 888.3510 21 CFR 888.3560
Product Code:	KRO JWH
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- GMK Revision, K102437, Medacta International SA

Reference Predicate

- GMK Hinge, K130299, Medacta International SA

IV. Device Description

The GMK Revision-Femoral Distal Augmentations have been designed to allow the surgeon to selectively fill bone deficiencies and to aid in adjusting the height of the joint line. In addition, these augments can help to achieve a stable fixation between the implant and the bone.

The purpose of this submission is to gain clearance for additional femoral distal augmentation thicknesses of 12 mm, 16 mm, and 20 mm, which can be used with the 5 mm thick posterior wedges. The previously cleared femoral distal augmentation sizes (referred to K102437 as femoral distal wedges) were for 4 mm, 8 mm, and 12 mm.

The subject devices are matched with the GMK Revision STD femoral component, GMK Revision PS femoral component and the GMK Hinge femoral component. The distal wedge is fixed to the femoral component through a thickness-specific titanium alloy screw packaged with it.

The GMK Revision-Femoral Distal Augmentations are manufactured from high nitrogen stainless steel, which is identical to the predicate device GMK Revision and GMK Hinge femoral distal augmentations (also referred to as wedges) which are available in size range 1-6 with thicknesses of 4 mm, 8 mm, and 12 mm.

V. Indications for Use

The GMK® Total Knee System 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 GMK HINGE knee prosthesis is designed for cemented use in total knee arthroplasty when the preoperative diagnosis of the joint determines that the bone and stability situation require the implantation of a constrained prosthesis.

The GMK HINGE knee system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis associated with bone loss and/or severe joint instability
- Considerable loss of function of the knee joint
- High-grade joint destruction requiring additional stabilization with stems and reconstruction of bone defects with metal augmentation
- Failure of a primary prosthesis (e.g. infection, loosening)
- Former revision arthroplasty
- Post traumatic loss of joint configuration

- Avascular necrosis of femoral condyle.

Tibial augmentation are to be screwed to the tibial baseplate with both the two provided fixing screws.
When a GMK HINGE® implant is used it is mandatory to implant both the femoral and tibial components with an extension stem.

VI. Comparison of Technological Characteristics

The GMK Revision-Femoral Distal Augmentations and the predicate devices share the following characteristics:

- Indications for Use
- Materials
- Packaging
- Design
- Use with both GMK Revision and GMK Hinge Femoral Components
- Sterile

The GMK Revision-Femoral Distal Augmentations is technologically different from the predicate devices as follows:

- Thickness sizes available
- Change to 12 mm augmentation, reduction in posterior side only

Biocompatibility testing conducted on the predicate device for the same material supports the biological safety of the GMK Revision-Femoral Distal Augmentations. Additional testing was not deemed necessary.

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

Technological comparison

Parameters	**Femoral Distal Augmentation (Subject Device)**	**GMK Revision Femoral Distal Wedge K102437 (Predicate Device)**
Design/Types	Distal femoral wedge with connection screw	Distal femoral wedge with connection screw
Material	High Nitrogen Stainless Steel (M30NW)	High Nitrogen Stainless Steel (M30NW
Sizes	Sizes 1-6	Sizes 1-6
Thickness	12 mm, 16 mm, 20 mm	4 mm, 8 mm, 12 mm
Compatibility with implant system	GMK Revision and GMK Hinge	GMK Revision and GMK Hinge
Device usage	Single Use	Single Use
Shelf Life	5 years	5 years

Parameters	Femoral Distal Augmentation (Subject Device)	GMK Revision Femoral Distal Wedge K102437 (Predicate Device)
Biocompatibility	Implant with permanent >30 day (Equivalency determined)	Implant with permanent >30 day
Sterilization	Gamma	Gamma
Packaging	Individual packaging	Individual packaging

Discussion
As seen above, the differences between the subject and predicate devices are the subject device are thicker than the predicate device. This technological difference does not raise new questions of safety or effectiveness and a comparison evaluation shows there are no new risks associated with the subject device design.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Studies

- Femoral Modular Connection- GMK-Revision Knee
- Femoral Modular Connection- GMK-Hinge Knee
- Limulus Amebocyte Lysate (LAL) testing was evaluated to establish the device meets pyrogen limit specifications.

Medacta previously conducted testing of the GMK Revision Femoral Component Size 1, GMK Revision Femoral Distal Wedge/ Augmentation Size 1 and GMK Revision Posterior Wedges Size 1, which are considered the worst-case product configuration as they have the least contact area, which makes the implant less able to fixate with cement. The results of the original testing showed that the worst-case product configuration is able to withstand physiological loads without any breakage and minimal fretting. The connection was stable and fixed after subjected to dynamic loading conditions. Since the femoral component, femoral distal wedge/augmentation and posterior wedges must all be the same size when implanted it is determined that the worst case remains unchanged. The data was previously submitted in the predicate 510(k) K102437. The test performed on the modular connection of the GMK-Revision implant are also applicable to the GMK-Hinge Femoral Component.

The Femoral Distal Augmentations 12 mm, 16 mm and 20 mm do not represent a worst-case configuration in terms of connection with the femoral components. The application of the load and the screwed connection are the same for all thicknesses.

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 Revision-Femoral Distal Augmentations are as safe and effective as the predicate devices. The addition of the new thicknesses of the subject device as compared to the predicate device, do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the GMK Revision-Femoral Distal Augmentations are substantially equivalent to the predicate devices.

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