November 1, 2017

Medacta International SA
% Roshana Ahmed
Associate Director, Regulatory Affairs
Mapi USA, Inc.
2343 Alexandria Drive
Suite 100
Lexington, Kentucky 40504

Re: k172347
Trade/Device Name: GMK Hinge, GMK Revision
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: August 3, 2017
Received: August 3, 2017

Dear Roshana Ahmed:

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 (DICE) 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 (DICE) 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)*

K172347

Device Name
GMK Hinge

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 augmentations are to be screwed to the tibial baseplate with both of 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.

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

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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)*

K172347

Device Name
GMK Revision

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

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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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: August 2, 2017

II. Device

Device Proprietary Name:	GMK Hinge and GMK Revision
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:

- GMK Hinge, K130299, Medacta International SA
- GMK Revision Extension, K123721, Medacta International SA

IV. Device Description

GMK Hinge:

This extension to the GMK Hinge product family consists of screwed tibial augmentations (thicknesses 15 and 20 mm) and Ultra Congruent (UC) fixed tibial inserts.

The tibial augmentations allow the surgeon to selectively fill bone deficiencies and to aid in restoring the joint line. The fixation between the augmentations and the tibial tray is assured by a screw fixation. The screwed tibial augmentations are manufactured from High Nitrogen Stainless Steel M30NW (ISO 5832-9). The tibial augmentation connection screws are manufactured from titanium alloy (Ti6Al4V; ISO 5832-3).

The UC fixed tibial insert is fixed to the tibial component through a screw and is designed to provide high rotational control and a high varus/valgus constraint. The UC fixed tibial inserts are manufactured from type 1 Ultra High Molecular Weight Polyethylene (UHMWPE; ISO 5834-2) and Cobalt-Chromium-Molybdenum alloy (CoCrMo; ISO 5832-12). The fixation screws are manufactured from titanium alloy (Ti6Al4V; ISO 5832-3).

GMK Revision:

This extension to the GMK Revision product family adds additional screwed tibial augmentations (thicknesses 15 and 20 mm) to the GMK Revision extension cleared under K123721. The tibial augments allow the surgeon to selectively fill bone deficiencies and to aid in restoring the joint line. The fixation between the augmentations and the tibial tray is assured by a screw fixation. The screwed tibial augmentations are manufactured from High Nitrogen Stainless Steel M30NW (ISO 5832-9). The tibial augmentation connection screws are manufactured from titanium alloy (Ti6Al4V; ISO 5832-3).

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V. Indications for Use

GMK Hinge:

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 augmentations are to be screwed to the tibial baseplate with both of 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.

GMK Revision:

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

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 Hinge and GMK Revision tibial augmentations share the following characteristics with the predicate devices:

- materials of construction;
- device size;
- device usage;
- connection with the tibial tray;
- method of fixation to the bone; and
- sterilization method.

The GMK Hinge and GMK Revision tibial augmentations are technologically different from the predicate devices as follows:

- greater thickness, and
- provided in RM/LL and LM/RL configurations.

The GMK Hinge and GMK Revision tibial augmentation connection screws are identical to those cleared under K130299 and K123721.

The GMK Hinge UC Fixed Tibial Inserts share the following characteristics with the predicate devices:

- materials of construction;
- device size and thickness;
- device usage; and
- sterilization method.

Comparisons between the subject and predicate devices are provided in the tables below.

	GMK Hinge	**GMK Hinge (K130299)**
Tibial Augmentations		
Material of Construction	High Nitrogen Stainless Steel M30NW (ISO 5832-9)	Same
Sterilization Method	Gamma Irradiation	Same
Device Usage	Single Use	Same
Sizes	S1 - S6	S0 – S6
Thickness	15 mm 20 mm	5 mm 10 mm
Configurations	Right medial, left lateral Left medial, right lateral	Symmetric
Shape	Tapered side	Straight side
Tibial Augmentation Connection Screws		
Material of Construction	Ti6Al4V (ISO 5832-3)	Same
Sterilization Method	Gamma Irradiation	Same
Device Usage	Single Use	Same
Dimensions	10 mm	Same
UC Fixed Tibial Inserts		
Materials of Construction	UHMWPE (ISO 5834 -2) CoCrMo (ISO 5832-12)	Same
Sterilization Method	Ethylene Oxide	Same
Device Usage	Single Use	Same
Sizes	S1 – S6	Same
Thickness	12 mm – 26 mm	Same
UC Fixed Tibial Insert Fixation Screws		
Material of Construction	Ti6Al4V (ISO 5832-3)	Same
Sterilization Method	Gamma Irradiation	Same
Device Usage	Single Use	Same
Dimensions	M4 x 8.5	Same

	GMK Revision	**GMK Revision (K123721)**
Tibial Augmentations		
Material of Construction	High Nitrogen Stainless Steel M30NW (ISO 5832-9)	Same
Sterilization Method	Gamma Irradiation	Same
Device Usage	Single Use	Same
Sizes	S1 – S6	S0 – S6
Thickness	15 mm 20 mm	5 mm 10 mm
Configurations	Right medial, left lateral Left medial, right lateral	Symmetric
Tibial Augmentation Screws		
Material of Construction	Ti6Al4V (ISO 5832-3)	Same
Sterilization Method	Gamma Irradiation	Same
Device Usage	Single Use	Same
Dimensions	10 mm	Same

Discussion

As seen above, the differences between the subject and predicate device tibial augmentations are the component thickness, configuration, and shape. These technological differences do not raise different questions of safety or effectiveness and the differences are addressed by performance data identified below.

VII. Performance Data

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

Non-Clinical Studies

- sterilization validation in accordance with ISO 11137-1:2006, ISO 11137-2:2006, and ISO 11135-1:2007;
- ethylene oxide residuals in accordance with ISO 10993-7:1995(R)2001;
- shelf life studies in accordance with ASTM F1980-07 (2011), ISO 11607-1:2006 and ISO 11607-2:2006;
- pyrogenicity testing (LAL Method);
- range of motion and rotational freedom evaluation;
- wear testing;
- static shear testing; and
- dynamic testing.

VIII. Conclusion

The information provided above supports that the GMK Hinge and GMK Revision are as safe and effective as their respective predicate devices. Although minor differences in design exist between the subject and predicate device tibial augmentation components, these differences are addressed by the performance testing included in this submission. Therefore, it is concluded that the GMK Hinge and GMK Revision system components are substantially equivalent to their respective predicate devices.