October 20, 2017

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

Re: K170106
Trade/Device Name: MyKnee® PPS-Pin Positioners
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: September 20, 2017
Received: September 21, 2017

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 (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,

Katherine D. Kavlock -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)*

K170106

Device Name
MyKnee® PPS-Pin Positioners

Indications for Use *(Describe)*

MyKnee® PPS-Pin Positioners are intended to be used as anatomical pin positioners specific for a single patient anatomy, to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting. MyKnee® PPS-Pin Positioners are intended for use with the GMK Total Knee System and its cleared indications for use. MyKnee® PPS-Pin Positioners are intended for single use only.

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: January 10, 2017
Date Revised: September 20, 2017

II. Device

Device Proprietary Name:	MyKnee® PPS-Pin Positioners
Common or Usual Name:	Total Joint Replacement
Classification Name:	Knee joint patellofemorotibial polymer/metal//polymer semi-constrained cemented prosthesis
Primary Product Code:	JWH
Regulation Number:	21 CFR 888.3560
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- MyKnee® Cutting Blocks, K093806, Medacta International SA

Reference Devices

- MySpine Pedicle Screw Placement Guides-LP, K153273, Medacta International SA
- GMK Total Knee System, K090988, Medacta International SA
- GMK-Line Extension, K120790, Medacta International SA (also referred to as GMK-Primary)
- GMK Sphere, K121416, Medacta International SA
- GMK Sphere Extension, K140826, Medacta International SA
- GMK Narrow, K122232, Medacta International SA (also referred to as GMK-Primary Narrow)

IV. Device Description

The purpose of this submission is to gain clearance for the MyKnee® PPS-Pin Positioners which is a line extension to the currently marketed MyKnee® Cutting Blocks (K093806). The integrated

cut slots have been removed to make the pin positioners suitable for use in Standard or MIS (muscle sparing approach) surgical techniques.

The MyKnee® PPS-Pin Positioners are single use femoral and tibial pin positioning patient-specific blocks. The MyKnee® PPS-Pin Positioners are designed and manufactured from patient MRI imaging data so the positioners match the patient's anatomy. The MyKnee® PPS-Pin Positioners are used with Medacta International SA's existing GMK Total Knee System, GMK Primary, GMK Sphere and GMK-Primary Narrow. The pin positioners are developed only for placement of the standard metal instruments (distal/tibial cut guide and 4-in-1 femoral cut guide) following the positions planned by the surgeon.

The MRI images are provided by the hospitals to Medacta International SA prepared according to a specific protocol for an individual patient. Medacta International SA uses these images in combination with Mimics (Materialise) and Solidworks (Dassault Systemes) to import DICOM images from a patient's MRI scans and these scans are then processed into accurate 3D models. The Solidworks validation plan and report were reviewed as part of the predicate 510(k) MyKnee® Cutting Blocks (K093806).

The MyKnee® PPS-Pin Positioners are manufactured from medical grade nylon for sintering which is identical to the predicate devices. MyKnee® PPS-Pin Positioners blocks are available in sizes 1-7 for the femur and sizes 1-6 for the tibia. The pin positioners will be provided in both non-sterile and sterile versions.

V. Indications for Use

MyKnee® PPS-Pin Positioners are intended to be used as anatomical pin positioners specific for a single patient anatomy, to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting. MyKnee® PPS-Pin Positioners are intended for use with the GMK Total Knee System and its cleared indications for use. MyKnee® PPS-Pin Positioners are intended for single use only.

VI. Comparison of Technological Characteristics

The MyKnee® PPS-Pin Positioners and the predicate devices share the following characteristics:

- indications for use;
- materials;
- packaging;
- sizes; and
- applicable mechanical axis.

The MyKnee® PPS-Pin Positioners are technologically different from the predicate devices as follows:

- design, removal of cut slots;
- image file applicable, MRI only; and
- sterile and non-sterile.

Biocompatibility testing was conducted on the predicate devices for the same material and testing supports the biological safety of the MyKnee® PPS-Pin Positioners. Additional biocompatibility testing was deemed unnecessary because the materials and manufacturing process are identical to the predicate devices described below.

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

Technological comparison

Parameter	**MyKnee® PPS-Pin Positioners (Subject Device)**	**MyKnee® Cutting Blocks K093806 (Predicate Device)**
Design/Types	Distal femoral and proximal tibial pin positioning blocks.	Distal femoral and proximal tibial cutting blocks.
Material	Medical Grade Nylon for sintering	Medical Grade Nylon for sintering
Sizes	Femoral blocks- Sizes 1-7 Tibial blocks- Sizes 1-6	Femoral blocks- Sizes 1-7 Tibial blocks- Sizes 1-6
Compatibility with implant system	GMK Total Knee System GMK Primary Femur (size 7) GMK Sphere GMK-Primary Narrow	GMK Total Knee System
Device usage	Single Use	Single Use
Shelf Life	6 months	6 months
Biocompatibility	Short term <24 hours contact (Equivalency determined)	Short term <24 hours contact Tested to ISO 10993-1, -5, -10
Sterilization	Non Sterile and Gamma	Non Sterile and Gamma
Packaging	Individual packaging	Individual packaging
Image Files Applicable	MRI	CT, MRI
Alignment Technique	Mechanical axis	Mechanical axis

Discussion
As seen above, the differences between the subject and predicate devices are the subject devices do not have an integrated cut slot like the predicate devices. This technological difference does not raise new questions of safety or effectiveness. A comparison evaluation shows there are no new risks associated with the subject devices design.

Medacta International SA has not made any changes to the patient contacting material of the subject devices which is identical to the predicate devices. There have been no changes to subject devices' sterilization method, sterilization process or packaging materials which are identical to the predicate devices.

VII. Performance Data

Based on the risk analysis, a design comparison and cadaver workshops were conducted according to written protocols. The following studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies

- design comparison (dimensional/geometrical);
- breakage evaluation;
- manufacturing process evaluation; and
- functional and fitting evaluation.

Sterilization

- sterilization dimensional and functional impact study; and
- gamma sterilization criticality assessment.

Clinical Studies

- no clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MyKnee® PPS-Pin Positioners are as safe and effective as the predicate devices. Although minor differences in design exist between the subject and predicate devices, the evaluation supports that the differences do not raise any new questions of safety or effectiveness. Therefore, it is concluded that the MyKnee® PPS-Pin Positioners are substantially equivalent to the predicate devices.