May 4, 2022

Medacta International S.A.
% Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K220705
Trade/Device Name: MyKnee R 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: March 9, 2022
Received: March 10, 2022

Dear Chris Lussier:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220705

Device Name
MyKnee R Pin Positioners

Indications for Use *(Describe)*

MyKnee® R Pin Positioners are intended for use as anatomical pin positioners specific for a single patient anatomy in case of revision total knee replacement. They are designed based on CT images of a patient's knee and the primary TKA implant in situ to assist in positioning the total knee replacement components intraoperatively and in guiding the marking of bone prior to cutting. MyKnee® R Pin Positioners are intended for single use only. Resections are performed through the standard or revision cutting guides. These are positioned on the pins placed in the holes drilled through the MyKnee® R Pin Positioner blocks after removal of the primary total knee implant components and according to the surgeon's preoperative planning. MyKnee® R Pin Positioners are intended for use with GMK® Primary, GMK® Sphere, GMK® SpheriKA, GMK® Revision, GMK® Hinge and their cleared indications for use.

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.

510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Sr. Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: March 9, 2022
Date Revised: May 3, 2022

II. Device

Device Proprietary Name:	MyKnee R Pin Positioners
Common or Usual Name:	Total Joint Replacement
Classification Name:	Knee joint patellofemorotibial polymer/metal//polymer semiconstrained cemented prosthesis
Primary Product Code:	JWH
Regulation Number:	21 CFR 888.3560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- MyKnee PPS-Pin Positioners, K170106, Medacta Interational SA

In addition, the following reference device is cited within the submission:

- My Knee Cutting Blocks, K093806, Medacta International SA

IV. Device Description

MyKnee R Pin Positioners are a line extension to the currently marketed MyKnee Cutting Blocks (K093806) and MyKnee PPS-Pin Positioners (K170106).

The MyKnee R blocks are single use, patient-specific pin positioner blocks designed based on CT images of a patient's knee and the primary TKA implant in situ.

They are intended to position the pins for placement of the standard instruments according to the surgeon's preoperative surgical planning.

The MyKnee R Pin Positioners are manufactured from medical grade nylon for sintering which is identical to the predicate devices.
They are available in left and right configuration with sizes 1-6 for the both the femurs and the tibia and, as the predicate devices, they can be provided in both non-sterile and sterile version.

V. Indications for Use

MyKnee® R Pin Positioners are intended for use as anatomical pin positioners specific for a single patient anatomy in case of revision total knee replacement. They are designed based on CT images of a patient's knee and the primary TKA implant in situ to assist in positioning the total knee replacement components intraoperatively and in guiding the marking of bone prior to cutting. MyKnee® R Pin Positioners are intended for single use only. Resections are performed through the standard or revision cutting guides. These are positioned on the pins placed in the holes drilled through the MyKnee® R Pin Positioner blocks after removal of the primary total knee implant components and according to the surgeon's preoperative planning. MyKnee® R Pin Positioners are intended for use with GMK® Primary, GMK® Sphere, GMK® SpheriKA, GMK® Revision, GMK® Hinge and their cleared indications for use.

VI. Comparison of Technological Characteristics

The subject MyKnee R Pin Positioners and the predicate MyKnee PPS Pin Positioners (K170106) are substantially equivalent with regards to the following characteristics:

- guide design;
- checking features;
- manufacturing process;
- material;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The MyKnee R Pin Positioners differs from the predicate device, MyKnee PPS Pin Positioners (K170106), with regards to the following characteristics:

- anchoring points;
- sizes range;
- instruments compatibility; and
- applicable image file.

Discussion

The slight differences between the subject and predicate devices do not raise new questions of safety and effectiveness. Medacta International SA has not made any changes to the manufacturing process, material, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices with respect to the predicate devices.
The comparison of technological characteristics and performance data provided within this submission, supports the substantial equivalence of the subject devices with respect to the predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validation and tests are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- Software validation;
- Cadaver testing validating subject devices' intended use, functional characteristics and features.

Biocompatibility data and sterilization validation studies submitted in support of the predicate devices were leveraged.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MyKnee R Pin Positioner are substantially equivalent to the predicate devices.