June 9, 2023

Medacta International S.A.
℅ Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K231037
Trade/Device Name: MyKnee UNI-ST
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: April 11, 2023
Received: April 12, 2023

Dear Christopher 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2023.06.09 15:09:46 -04'00'

FOR: Lixin Liu
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.

Submission Number *(if known)*

K231037

Device Name

MyKnee UNI-ST

Indications for Use *(Describe)*

The MyKnee UNI-ST blocks are based on CT or MRI scans of the knee and they are intended for use as anatomical cutting blocks or pin positioners specifically designed for each patient to assist in the intraoperative positioning of the tibial unicompartmental component and to guide the marking of the bone before cutting.
The MyKnee UNI-ST blocks are intended for use with MOTO Partial Knee systems when the clinical evaluation complies with clear indications for use. MyKnee UNI-ST blocks 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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: April 11, 2023

II. Device

Device Proprietary Name:	MyKnee UNI-ST
Common or Usual Name:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained 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 Cutting Blocks, K093806, Medacta International SA.

Additionally, the following reference device is used within the submission:

- MyKnee R Pin Positioners, K220705, Medacta International SA.

IV. Device Description

MyKnee UNI-ST are a line extension to the currently marketed MyKnee Cutting Blocks (K093806), MyKnee PPS-Pin Positioners (K170106) and MyKnee R Pin Positioners (K220705).
The MyKnee UNI-ST are single use, patient-specific tibial cutting blocks which allows the surgeon to carry out the tibial resection according to the preoperative 3D plan based on CT or MRI images of the patient's knee.
The MyKnee UNI-ST cutting blocks are available in left and right medial configuration with a range of sizes covering the whole MOTO tibial implant portfolio for which they are intended for use with.

Identically to the predicate devices, the MyKnee UNI-ST are manufactured from medical grade nylon for sintering and they can be provided in both non-sterile and sterile version.

V. Indications for Use

The MyKnee UNI-ST blocks are based on CT or MRI scans of the knee and they are intended for use as anatomical cutting blocks or pin positioners specifically designed for each patient to assist in the intraoperative positioning of the tibial unicompartmental component and to guide the marking of the bone before cutting.
The MyKnee UNI-ST blocks are intended for use with MOTO Partial Knee systems when the clinical evaluation complies with clear indications for use. MyKnee UNI-ST blocks are intended for single use only.

VI. Comparison of Technological Characteristics

The subject MyKnee UNI-ST cutting blocks are substantially equivalent to the predicate device, MyKnee cutting blocks (K093806), with regards to the following characteristics:

- Checking features;
- Applicable images file;
- Manufacturing process;
- Material;
- Biocompatibility;
- Device usage;
- Shelf-life; and
- Packaging.

The subject MyKnee UNI-ST cutting blocks differs respect to the predicate, MyKnee cutting blocks (K093806), with regards to the following characteristics:

- Sizes;
- Anchoring points; and
- Instruments compatibility.

Discussion
The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness.
Medacta International SA has not made any change 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 the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

Based on the risk analysis, performance testing was conducted to written protocols. The following validations are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *Design validation*
  - Sawbone workshop verifying the functionality of the subject devices for their intended use;
  - Dimensional analysis to demonstrate that the subject devices do no not introduce a new worst case with respect to mechanical resistance; and
  - Cadaver testing validating the accuracy of the subject devices' placement on the bone and the accuracy of the resection performed.
- Biocompatibility data, shelf-life 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 subject devices are substantially equivalent to the predicate devices.