March 10, 2022

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

Re: K213751
Trade/Device Name: NextAR™ TKA Platform My Knee PPS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, JWH, PBF
Dated: December 17, 2021
Received: December 20, 2021

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: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K213751

Device Name
NextAR™ TKA Platform My Knee PPS

Indications for Use *(Describe)*
The NextAR™ Knee Platform is intended to be used to support the surgeon during total knee replacement procedures by providing information on bone resections, ligaments behavior, instrument and implant positioning.

The NextAR™ Knee Platform is intended to be used in combination with NextAR™ stereotaxic instruments and general surgical instruments to implant the GMK® Sphere Total knee system and perform ligament balancing. As an optional display, the smart glasses can be used auxiliary to the NextAR™ Platform to view the same 2D stereotaxic information as presented by the NextAR™ Platform.

The smart glasses should not be relied upon solely and should always be used in conjunction with the primary computer display.

The MyKnee® NextAR™ cutting guides include a camera/target holder and a PSI MyKnee® cutting guide both for tibia and femur. The MyKnee® cutting guides must be used as anatomical cutting blocks 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.

The MyKnee® PPS NextAR™ blocks include a PSI MyKnee® pin positioners block both for tibia and femur. The MyKnee® PPS NextAR™ blocks must be used as anatomical Pin positioners blocks 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.

The use of MyKnee® NextAR™ cutting guides or MyKnee® PPS NextAR™ blocks are applicable only for the "PSI-based" approach. MyKnee® NextAR™ cutting guides or MyKnee® PPS NextAR™ blocks are for single use only.

The NextAR™ stereotaxic instruments are intended to be used to support the surgeon during specific orthopedic surgical procedures by providing information on bone resections, ligaments behavior, instrument and implant positioning. The NextAR™ Knee stereotaxic instruments, when registered with the MyKnee® NextAR™ Knee cutting guides, provide reference to a patient's rigid anatomical structures, such as the femur and tibia, that can be identified relative to pre-operative CT based planning.

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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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 Affairs Director, Medacta International SA
Applicant Correspondent: Christopher Lussier, Sr. Director, Quality and Regulatory, Medacta USA

Date Prepared: November 29, 2021
Date Revised: February 23, 2022

II. Device

Device Proprietary Name:	NextAR™ TKA Platform My Knee PPS
Common or Usual Name:	Navigation System Total Joint Replacement
Classification Name:	Stereotaxic Instrument Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Primary Product Code:	OLO JWH PBF
Regulation Number:	21 CFR 882.4560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- NextAR™ TKA Platform, K202152
- NextAR™ TKA Platform, K193559

Additional predicate device:

- MyKnee® NextAR™ Cutting Blocks, K193559, Medacta International SA
- MyKnee® Pin Positioners, K170106, Medacta International SA

IV. Device Description

The NextAR™ TKA Platform is a CT based computer-assisted surgical navigation platform used in total knee replacement surgery and includes the following components:

- Navigation software which displays information to the surgeon in real-time;
- Augmented Reality glasses;
- Optical tracking system;
- PC based hardware platform;
- MyKnee NextAR Cutting Blocks (PSI) - an option;
- MyKnee NextAR Pin Positioners (PPS) - an option; and
- Reusable surgical instruments for total knee replacement procedures.

NextAR™ TKA Platform PSI based is available on the US market via the clearance - K193559.

NextAR™ TKA Platform PSI free is available on the US market via the clearance - K202152.

The system operates on the common principle of stereotaxic technology in which markers are mounted on the bones and an infrared camera is used to monitor the spatial location of the markers. Tracking sensors attached to the bones enable the surgeon to view the position and orientation of bones and instrumentation relative to preoperative data in real-time while performing the surgical procedure. The tracking sensors are provided sterile. In NextAR TKA MyKnee PPS, subject of the submission, the placement of the sensor is performed by the use of reusable metal instrumentation used in the PSI free version (NextAR™ TKA Platform, K202152).

The NextAR™ TKA Platform PSI based, PSI free and now NextAR™ TKA MyKnee PPS aid the surgeon in executing the surgical plan by visualizing all the information in real time in a screen monitor. Utilizing the approach NextAR™ TKA Platform PSI based (K193559) the placement of the implants is performed by cutting the bones using MyKnee® NextAR™ Cutting Blocks and, optionally, utilizing the approach NextAR™ TKA Platform PSI free (K202152), the placement of the implants is performed by cutting the bones using navigated reusable surgical instrumentation where the registration of the CT scan of the patient's anatomy is performed by executing the NextAR registration algorithm. Now, NextAR™ TKA MyKnee PPS fuses features from both PSI and PSI free method. NextAR PPS helps the surgeon to place the metal fixation for the sensor and the pins to place the standard or micrometric cutting guides to reproduce the preoperative planning.

Same reusable surgical instrumentation (provided non-sterile) guided by the tracking sensors can be used also for recut. Although the position of the implants can be validated to assess the correct

execution of the planning, the surgeon can change the surgical plan intraoperatively by analyzing the 3D models of the patient, the CT scan, and the 3D geometry of the implants.

With this submission we are presenting the NextAR™ TKA MyKnee PPS intended to be used in combination with NextAR™ PSI guide together with the metal fixation and a similar registration algorithm of the NextAR PSI free (K202152) to implant the GMK® Sphere Total knee system and perform ligament balancing. The NextAR™ TKA MyKnee PPS needs only five (5) points on the PSI PPS block to be acquired for the registration.

The MyKnee® NextAR™ Pin Positioners, manufactured from medical grade nylon, are single use patient-specific blocks which are designed from patient CT images. They are intended to position the pins for placement of the standard instruments and for the infrared technology. The blocks are provided sterile via gamma irradiation or non-sterile.

The surgeon can choose the desired approach, PSI-based (clearance - K193559), PSI-free (clearance - K202152), or PPS now under submission.

V. Indications for Use

The NextAR™ Knee Platform is intended to be used to support the surgeon during total knee replacement procedures by providing information on bone resections, ligaments behavior, instrument and implant positioning.

The NextAR™ Knee Platform is intended to be used in combination with NextAR™ stereotaxic instruments and general surgical instruments to implant the GMK® Sphere Total knee system and perform ligament balancing. As an optional display, the smart glasses can be used auxiliary to the NextAR™ Platform to view the same 2D stereotaxic information as presented by the NextAR™ Platform.

The smart glasses should not be relied upon solely and should always be used in conjunction with the primary computer display.

The MyKnee® NextAR™ cutting guides include a camera/target holder and a PSI MyKnee® cutting guide both for tibia and femur. The MyKnee® cutting guides must be used as anatomical cutting blocks 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.

The MyKnee® PPS NextAR™ blocks include a PSI MyKnee® pin positioners block both for tibia and femur. The MyKnee® PPS NextAR™ blocks must be used as anatomical Pin positioners blocks 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.

The use of MyKnee® NextAR™ cutting guides or MyKnee® PPS NextAR™ blocks are applicable only for the "PSI-based" approach. MyKnee® NextAR™ cutting guides or MyKnee® PPS NextAR™ blocks are for single use only.

The NextAR™ stereotaxic instruments are intended to be used to support the surgeon during specific orthopedic surgical procedures by providing information on bone resections, ligaments behavior, instrument and implant positioning. The NextAR™ Knee stereotaxic instruments, when registered with the MyKnee® NextAR™ Knee cutting guides, provide reference to a patient's rigid anatomical structures, such as the femur and tibia, that can be identified relative to pre-operative CT based planning.

VI. Comparison of Technological Characteristics

The NextAR™ TKA MyKnee PPS and the predicate NextAR™ TKA Platform PSI Free share the following characteristics:

- principle of operation;
- user interface;
- power source;
- surgical workflow;
- main system components; with MyKnee NextAR Cutting Blocks;
- use of surgical instruments for navigation;
- orientation and positioning of bone resections; and
- device accuracy.
- use of active optical tracking system;
- computer hardware; and
- pre-operative patient anatomy data acquisition.

The NextAR™ TKA Platform PPS and the predicate NextAR™ TKA Platform PSI free are technologically different with respect to:

- registration of sensor position through updated algorithm, intra-operatively.
- use of MyKnee NextAR Pin Positioners.

The MyKnee® NextAR™ Pin Positioner and the predicate devices (MyKnee® NextAR™ Cutting Blocks and MyKnee® Pin Positioners) share the following characteristics:

- material of construction;
- manufacturing process;
- size and dimensions;
- sterilization method; and
- packaging.

Only for the Tibial MyKnee® NextAR™ Pin Positioners and the predicate device MyKnee NextAR Cutting Blocks there is a technologically difference with respect to the number of contact point positions only for the Tibial pin positioner that are shared with the predicate device MyKnee® Pin Positioners.

Discussion

There are minor differences between the subject and predicate devices; these differences are concerning the registration of the position of sensors with respect to the bones through the use of an updated algorithm and the use of MyKnee NextAR Pin Positioner.

They do not raise different questions of safety or effectiveness when compared to the predicate devices. Both navigation systems utilize stereotaxic technologies within the same surgical workflow. Minor differences are addressed by performing in vitro validation/rational.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following studies were performed in support of a substantial equivalence determination:

- software validation;
- in vitro validation

The following studies were accepted during the submission of the predicate NextAR™ TKA Platform PSI based K193559 and PSI free K202152 and they are unchanged.

- biocompatibility per ISO 10993-1:2009;
- sterilization validation;
- shelf-life testing;
- electrical safety testing per IEC 60601-1:2005, COR1:2006, COR2:2007, Amd1:2012;
- electromagnetic compatibility testing per IEC 60601-1-2:2014;
- performance testing to evaluate mechanical and optical properties.

VIII. Conclusion

The information provided above supports that the NextAR™ TKA MyKnee PPS is substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations. The NextAR™ TKA MyKnee PPS can be considered substantially equivalent to the identified predicate devices.