Medacta International SA
% Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

October 27, 2020

Re: K202152
Trade/Device Name: NextAR TKA Platform
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, JWH, PBF
Dated: July 31, 2020
Received: August 3, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202152

Device Name
NextAR™ TKA Platform

Indications for Use *(Describe)*

The NextAR™ TKA Platform is intended to be used to support the surgeon during total knee replacement procedures by providing information on bone resections, ligaments behaviour, instruments and implants positioning.

The NextAR™ TKA 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 use of MyKnee® NextAR™ cutting guides are applicable only for the "PSI-based" approach. MyKnee® NextAR™ TKA cutting guides 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™ stereotaxic instruments, when registered with the MyKnee® NextAR™ TKA 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.

510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Director, Medacta International SA
Applicant Correspondent: Christopher Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: October 8, 2020

II. Device

Device Proprietary Name:	NextAR™ TKA Platform
Common or Usual Name:	Navigation System Total Joint Replacement
Classification Name:	Stereotaxic Instrument Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Product Codes:	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 K193559

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) – now an option
- Reusable surgical instruments for total knee replacement procedures.

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

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.

The NextAR™ TKA Platform PSI based and PSI free, aid the surgeon in executing the surgical plan by visualizing all of the information in real time via a monitor.

The approach currently cleared via K193559, is to utilize the NextAR™ TKA Platform – PSI for the placement of the implants by cutting the bones using the MyKnee® NextAR™ Cutting Blocks.

The subject of this submission is to add an optional approach for the surgeon to utilize the NextAR™ TKA Platform PSI free for the placement of the implants by cutting the bones using navigated, reusable surgical instrumentation (provided non-sterile). The registration of the CT scan on the patient's anatomy is performed by executing the NextAR registration algorithm.

The same reusable surgical instrumentation (provided non-sterile) that is 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 Platform extension (PSI free) 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.

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

V. Indications for Use

The NextAR™ TKA Platform is intended to be used to support the surgeon during total knee replacement procedures by providing information on bone resections, ligaments behaviour, instruments and implants positioning.

The NextAR™ TKA 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.

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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™ stereotaxic instruments, when registered with the MyKnee® NextAR™ TKA 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 Platform PSI free and the predicate NextAR™ TKA Platform PSI based share the following characteristics:

- principle of operation;
- user interface;
- power source;
- surgical workflow;
- main system components; except 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;
- pre-operative patient anatomy data acquisition.

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

- registration of sensor position through dedicated algorithm, intra-operatively.

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 a dedicated algorithm. They do not raise different questions of safety or effectiveness when compared to the predicate device. Both navigation systems utilize stereotaxic technologies within the same surgical workflow. Minor differences are addressed by performing cadaveric testing/ 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;
- cadaver study.

The following studies were accepted during the submission of the predicate NextAR™ TKA Platform PSI based K193559 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 Platform Extension (PSI free) 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 Platform Extension (PSI free) can be considered substantially equivalent to the identified predicate devices.