510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA

Date Prepared: January 19, 2021

II. Device

Device Proprietary Name:	NextAR™ RSA Platform
Common or Usual Name:	Navigation System Total Joint Replacement
Classification Name:	Stereotaxic Instrument
Product Codes:	OLO PBF LLZ PHX
Regulation Number:	21 CFR 882.4560, 21 CFR 888.3030, 21 CFR 892.2050, 21 CFR 888.3660
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- ExactechGPS K173372

Reference predicate devices:

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

IV. Device Description

The Shoulder NextAR™ RSA Platform is a CT based computer-assisted surgical navigation platform used to perform a reverse shoulder arthroplasty on the glenoid and includes the following components:

- PC based hardware platform; (K193559 and K202152)
- optical tracking system; (K193559 and K202152)
- Augmented Reality glasses; (K193559 and K202152)
- Platform (K193559 and K202152)
- navigation software which displays information to the surgeon in real-time;
- Reusable surgical instruments to perform the surgical steps of a shoulder reverse arthroplasty on the glenoid.

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 scapula and surgical instruments enable the surgeon to view the position and orientation of scapula and instrumentation relative to preoperative data in real-time while performing the surgical procedure. The tracking sensors are provided sterile.

Shoulder NextAR™ RSA Platform aids the surgeon in executing the surgical plan by visualizing all the information in real time on a screen monitor.
The NextAR™ RSA system is intended to assist the surgeon in executing a preoperative surgical planning. The navigation platform tracks the surgical instruments in real-time and displays intraoperative and planned surgical parameters on a screen, thus allowing the surgeon to match the intraoperative parameters with the planned ones.

Specifically, the navigation system utilizes established technologies of navigation and via an active infrared camera rigidly coupled with the scapula and an active infrared tracker that can be rigidly coupled to the surgical instruments. The registration of the patient's scapula on the preoperative scapula model is performed through the use of dedicated surgical instruments (pointers) and a dedicated registration algorithm.

V. Indications for Use

The Shoulder NextAR™ RSA Platform supports the surgeon during glenoid implantation in reverse shoulder replacement procedures providing information on bone preparation, instrument guidance, and implant positioning.
The Shoulder NextAR™ RSA Platform works in conjunction with NextAR™ stereotaxic instruments and general surgical instruments to implant the Medacta Shoulder System Reverse (RSA – Reverse Shoulder Arthroplasty). As an optional display, the smart glasses can be used

auxiliary to the Shoulder NextAR™ Platform to view the same 2D stereotaxic information as presented by the Shoulder NextAR™ Platform.
The Shoulder NextAR™ stereotaxic instruments are to support the surgeon during specific orthopedic surgical steps by providing information on bone preparation, instrument guidance, and implant positioning. Once registered, the NextAR™ stereotaxic instruments provide reference to a patient's rigid anatomical structures on the surface of the glenoid that are identified relative to preoperative C.T. based planning.
The smart glasses should not be relied upon solely and should always be used in conjunction with the primary computer display.

VI. Comparison of Technological Characteristics

Shoulder NextAR™ RSA Platform and the predicate Exactech GPS Shoulder (K173372) share the following characteristics:

- Indications for use
- Main system components
- Imaging
- Graphical User interface
- Surgical workflow
- Bone registration
- Planned and controlled parameters
- Surgical instruments for navigation

Shoulder NextAR™ RSA Platform and the predicate NextAR™ TKA Platform K202152 share the following characteristics:

- principle of operation;
- power source;
- system components;
- use of active optical tracking system
- computer hardware;
- registration of anatomy;
- Sterility;
- Biocompatibility

Shoulder NextAR™ RSA Platform and the predicate Exactech GPS Shoulder (K173372) are technologically different in the following features:

- The camera is attached to the instruments. No need for an external camera.
- Use of K-wire during the surgical workflow;
- Glenosphere placement/rotation during the surgical workflow.

Shoulder NextAR™ RSA Platform and the predicate NextAR™ TKA Platform K202152 are technologically different with respect to:

- Indications for use;
- Software for navigation;
- Surgical instruments

Discussion

There are minor differences between the subject and predicate devices; these differences concern the camera location, glenosphere placement and the use of the K-wire when compared to the main predicate K173372.
Comparing the subject device to the reference predicate K202152 NextAR TKA Platform the differences are the indication for use, software for navigation and dedicated instruments.

These differences do not raise questions of safety or effectiveness. Both navigation systems utilize stereotaxic technologies. Minor differences are addressed by performing cadaveric testing and 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;
- In vitro study

The following studies were accepted during the submission of the predicate NextAR™ TKA Platform PSI based K193559 and 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 Shoulder NextAR™ RSA Platform 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 Shoulder NextAR™ RSA Platform can be considered substantially equivalent to the identified predicate devices.

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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)*

K210153

Device Name
NextAR™ RSA Platform

Indications for Use *(Describe)*

The Shoulder NextAR™ RSA Platform supports the surgeon during glenoid implantation in reverse shoulder replacement procedures providing information on bone preparation, instrument guidance, and implant positioning.
The Shoulder NextAR™ RSA Platform works in conjunction with NextAR™ stereotaxic instruments and general surgical instruments to implant the Medacta Shoulder System Reverse (RSA – Reverse Shoulder Arthroplasty). As an optional display, the smart glasses can be used auxiliary to the Shoulder NextAR™ Platform to view the same 2D stereotaxic information as presented by the Shoulder NextAR™ Platform.

The Shoulder NextAR™ stereotaxic instruments are to support the surgeon during specific orthopedic surgical steps by providing information on bone preparation, instrument guidance, and implant positioning. Once registered, the NextAR™ stereotaxic instruments provide reference to a patient's rigid anatomical structures on the surface of the glenoid that are identified relative to preoperative C.T. based planning.

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

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)

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May 12, 2021

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

Re: K210153
Trade/Device Name: NextAR RSA Platform
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, PBF, LLZ, PHX
Dated: April 9, 2021
Received: April 13, 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