October 29, 2023

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

Re: K232280
Trade/Device Name: NextAR™ TSA Platform
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, JWH
Dated: July 28, 2023
Received: July 31, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

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)*

K232280

Device Name
NextAR™ TSA Platform

Indications for Use *(Describe)*

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

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."

K232280
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, Senior Director, Quality, Regulatory, and Clinical Research Medacta USA.
Date Prepared: July 28, 2023

II. Device

Device Proprietary Name:	NextAR™ TSA Platform
Common or Usual Name:	Navigation System Total Joint Replacement
Classification Name:	Stereotaxic Instrument
Primary Product Code: Secondary Product Codes:	OLO PBF LLZ PHX
Regulation Number:	21 CFR 882.4560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:
NextAR™ RSA Platform K210153

Reference predicate devices:
NextAR Spine K223769

IV. Device Description

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

- PC based hardware platform; (K210153)
- optical tracking system; (K210153)
- Augmented Reality glasses; (K210153)
- Platform (K210153)
- navigation software which displays information to the surgeon in real-time;
- Reusable surgical instruments to perform the surgical steps of a shoulder anatomic 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 register 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™ TSA Platform aid the surgeon in executing the surgical plan by visualizing all the information in real time in a screen monitor.
The NextARTM TSA 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 NextAR Shoulder™ Platform supports the surgeon during glenoid implantation in anatomic shoulder replacement procedures providing information on bone preparation, instrument guidance, and implant positioning.
The NextAR Shoulder™ Platform works in conjunction with NextAR™ stereotaxic instruments and general surgical instruments to implant the Medacta Shoulder System Anatomic (TSA – Total Shoulder Arthroplasty). As an optional display, the smart glasses can be used auxiliary to the

NextAR Shoulder™ Platform to view the same 2D stereotaxic information as presented by the NextAR Shoulder™ Platform.
The NextAR Shoulder™ stereotaxic instruments are to support the surgeon during specific orthopedic surgical procedures 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™ TSA Platform and the predicate NextAR™ RSA Platform K210153 share the following characteristics:

- principle of operation;
- power source;
- system components;
- surgical workflow (except dedicated anatomic surgical steps)
- bone registration algorithm
- use of active optical tracking system
- computer hardware;
- registration of anatomy;
- surgical instruments for navigation
- sterility;
- biocompatibility

Shoulder NextAR™ TSA Platform and the predicate NextAR Spine K223769

share the following characteristics:

- glasses communication;

Shoulder NextAR™ TSA Platform and the predicate NextAR™ RSA Platform K210153 are technologically different with respect to:

- Indications for use;
- Software for navigation;
- Surgical workflow (added dedicated anatomic surgical steps)
- Surgical instruments

For both NextAR™ RSA and NextAR™ TSA the registration algorithm has not changed but the glenoid registration is now completed with 6+20 points instead of 4+30 that was included in the previous version.

Discussion

There are minor differences between the subject and predicate devices;
Comparing the subject device to the main predicate NextAR™ RSA Platform K210153 the differences are the indication for use, software for navigation and dedicated instruments.
They do not raise different 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;
- rational on glenoid registration

The following studies were accepted during the submission of the predicates NextAR™ RSA K210153 and NextAR Spine K223769 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.
- glasses communication

VIII. Conclusion

The information provided above supports that the Shoulder NextAR™ TSA 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™ TSA Platform can be considered substantially equivalent to the identified predicate devices.