September 4, 2025

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

Re: K251737
Trade/Device Name: NextAR(TM) Shoulder Platform
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: June 6, 2025
Received: June 6, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251737 ?

Please provide the device trade name(s). ?

NextAR™ Shoulder Platform

Please provide your Indications for Use below. ?

The NextAR Shoulder™ Platform supports the surgeon during glenoid implantation in anatomic and reverse 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 shoulder prosthesis.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C) ?

510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Date Prepared: August 29, 2025

II. Device

Device Proprietary Name:	NextAR™ Shoulder Platform
Common or Usual Name:	Orthopedic stereotaxic instrument
Classification Name:	Orthopedic Augmented Reality
Primary Product Code	SBF
Regulation Number:	21 CFR 882.4560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- NextAR™ TSA Platform, K232280, Medacta International SA

Additional Predicate devices:

- NextAR RSA Platform, K210153, Medacta International SA
- Glenoid Reconstruction System – Full Wedge Baseplate, K231911, Medacta International SA
- Glenoid Reconstruction System, K213459, Medacta International SA
- NextAR TKA Platform, K193559, Medacta International SA
- Medacta Shoulder System, K170452, Medacta International SA

IV. Device Description

The NextAR™ Shoulder 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 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.

NextAR™ Shoulder Platform aids the surgeon in executing the surgical plan by visualizing all the information in real time in a screen monitor.

The NextAR™ Shoulder 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 and reverse 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 shoulder prosthesis.

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

The subject NextAR™ Shoulder Platform and the predicate device (K232280, K210153) are substantially equivalent with respect to the following characteristics:

- Main system components;
- Power source;
- User interface;
- Glasses communication;

- Registration features;
- Planned and controlled parameters; and
- Instruments' materials and sterility.

The only differences between the subject NextAR™ Shoulder Platform and the predicate devices (K232280, K210153) are the additional workflow steps introduced for reverse shoulder arthroplasty.

Discussion
The additional step of the subject device available in the surgical workflow do not introduce any differences on safety and performance with respect to the steps in the predicate devices (K232280, K210153), since they are surgical steps substantially equivalent to already existing ones.

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, testing activities were conducted to written protocols. The following validations and tests are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- Software verification and validation
- Cadaver workshop to qualitively validate that the subject instruments are adequate for their intended use
- The biocompatibility evaluation of the instruments leveraged equivalence in materials and manufacturing to previously cleared instruments (K232280)

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.