July 31, 2025

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

Re: K250477
Trade/Device Name: NextAR™ Spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: February 19, 2025
Received: June 30, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250477

Device Name

NextAR™ Spine

Indications for Use *(Describe)*

• NextAR Spine platform
The NextAR Spine platform is intended as an aid for precisely locating anatomical structures in either open/mini-open or percutaneous spine procedures. It is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, when reference to a rigid anatomical structure, such as vertebrae or pelvis, can be identified relative to images of the anatomy. This can include posterior approach spinal procedures, such as:
• Pedicle Screw Placement (Thoracic and Lumbosacral spine)
• Sacro-Iliac Screw Placement

NextAR Spine is also intended to provide planning tools for measuring and selecting the fixation rod for the thoracic and lumbosacral spine.

The NextAR Spine platform is intended to be used in combination with NextAR™ Stereotaxic instruments and / or Medacta preoperative planning. In the case of pre-operative planning, surgical planning software is used pre-operatively to plan the surgical placement of pedicle screws based upon radiological images of the patient. As an optional display, the NextAR Smart Glasses can be used auxiliary to the NextAR Spine Platform to view stereotaxic information as presented by the NextAR Spine Platform. The NextAR Smart Glasses should not be relied upon solely and should always be used in conjunction with the primary computer display.

• NextAR Spine sterile drill and pins
The sterile drills, pins and iliac pins are part of the NextAR Spine platform which is intended as an aid for precisely locating anatomical structures in either open / mini open or percutaneous spine procedures. The NextAR Spine sterile drills pins and iliac pins are intended for use with the NextAR Spine platform according to its approved indications for use. All the drills are motorized. Pins may be used either motorized or manually. Iliac pins are manual.

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.

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"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."

510(k) Summary

I. Submitter

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

Date Prepared: February 19, 2025
Date Revised: July 33, 2025

II. Device

Device Proprietary Name:	NextAR™ Spine
Common or Usual Name:	Navigation System Total Joint Replacement
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 devices:
Primary predicate device

- NextAR™ Spine Platform K233172, Medacta International SA

Additional predicate device

- NextAR™ Spine Platform K210859, Medacta International SA

IV. Device Description

The NextAR™ Spine platform is a CT based computer-assisted surgical navigation platform used in either open/mini open or percutaneous spine surgery procedure and includes the following components:

- Navigation software which displays information to the surgeon
- Augmented Reality glasses
- Optical tracking system
- PC based hardware platform
- Fiducial Block
- Surgical instruments for spine surgery procedures

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 instruments. Tracking sensors attached to the bones enable the surgeon to view the position and orientation of the instrumentation relative to the intra-operative data in real-time while performing the surgical procedure. The tracking sensors, the fiducial block, and a group of pins and drills are provided sterile.

NextAR™ Spine aids the surgeon in executing the surgical plan by visualizing all the information in real time in a screen monitor. The platform uses the information of either an intra-operative scan or pre-operative CT in combination with an intra-operative 3D scan in order to register the spine to navigation elements. The registration can be performed with one of the following approaches: 1) Direct 3D: based on the use of an intra-operative 3D scan, or 2) 3D-3D: based on the use of a pre-operative CT scan and an intra-operative 3D scan.

Where the Direct 3D approach is utilized, NextAR™ Spine allows for planning of screw positioning on the patient's intraoperative DICOM images just before system setup. The application allows for navigating the spine with a screw planning superimposed on the acquired scan.

The NextAR™ Spine platform also includes the rod planning tool, which gives the surgeon information about the length and the rod type to best fit the spine anatomy and to perform the desired curvature correction.

The system's navigation technology is based on an active infrared camera coupled with an active tracker (Target). These elements allow, by means of the different registration approaches and use of compatible instruments, to accurately prepare trajectories in the vertebrae and/or to implant screws while visualizing information in real time on a screen monitor.

V. Indications for Use

- NextAR Spine platform

The NextAR Spine platform is intended as an aid for precisely locating anatomical structures in either open/mini-open or percutaneous spine procedures. It is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, when reference to a rigid anatomical structure, such as vertebrae or pelvis, can be identified relative to images of the anatomy. This can include posterior approach spinal procedures, such as:

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VI. Comparison of Technological Characteristics

The subject and predicate device (K233172) share the following characteristics:

- principle of operation
- user interface
- power source
- optical tracking system
- platform
- displaying technology
- glasses communication
- use of surgical instruments for navigation
- main system components
- use of surgical instruments for navigation

- tracking system accuracy
- use of active optical tracking system
- computer hardware
- pre-operative patient anatomy data acquisition
- intra-operative patient anatomy data acquisition
- use of surgical instruments for navigation
- rod planning and intra operative screw planning features
- fiducial registration accuracy
- instruments' materials and sterility.

The biocompatibility evaluation of the subject instruments leveraged identical materials and manufacturing to previously cleared instruments (K210859 and K200391).

The main difference between the subject and predicate device (K233172) is the possibility to navigate new instruments and use new target mountings. The new instruments to be used in conjunction with the navigation platform, are substantially equivalent to the instruments already cleared within the additional predicate device (K210859).

VII. Performance Data

Non-Clinical Studies:
The following verification and validation activities have been performed in support of a substantial equivalence determination:

- Software testing
- Comparative evaluations to demonstrate that the subject instruments are substantially equivalent to the predicate instruments used with NextAR Spine and cleared within K210859
- Cadaver workshops to demonstrate that the subject instruments are adequate for their intended use

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the NextAR^{TM} Spine is substantially equivalent to the predicate devices.