April 24, 2024

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

Re: K233172
Trade/Device Name: NextAR™ Spine Platform
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, JWH, PBF
Dated: September 27, 2023
Received: September 28, 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,

Tejen D. Soni -S

For
Shumaya Ali, MPH
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)*

K233172

Device Name
NextAR™ Spine Platform

Indications for Use *(Describe)*

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)
- Iliosacral 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 NextARTM 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.

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.

K233172
510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Director, Medacta International SA Applicant
Correspondent: Christopher Lussier, Sr. Director of Quality and Regulatory, Medacta USA
Date Prepared: September 25, 2023
Date Modified: April 24, 2024

II. Device

Device Proprietary Name:	NextAR™ Spine Platform
Common or Usual Name:	Navigation System Total Joint Replacement
Classification Name:	Stereotaxic Instrument
Primary Product Code:	OLO JWH PBF
Regulation Number:	21 CFR 882.4560, 21 CFR 888.3560, 21 CFR 888.3030
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- NextAR™ Spine Platform K223769 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;
- Adaptor for sensor:
- Spine attachment instruments
- Reusable 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.

The NextAR™ Spine Platform aid the surgeon in executing the surgical plan by visualizing all the information in real time in a screen monitor.

The NextAR Spine system is a surgical navigation platform which 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:

- Direct 3D: based on the use of an intra-operative 3D scan
- 3D-3D: based on the use of a pre-operative CT scan and an intra-operative 3D scan

NextAR gives the possibility of planning the screw positioning on the intraoperative DICOM images of the patient, in case of the 3D direct approach, just before the system setup.
The application allows for navigating the spine with a screw planning superimposed on the acquired scan.

The NextAR Spine Platform includes also the rod planning that is intended to provide information on the length and geometry of the pre-bend rod that would fit with each screw position.

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

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)
• Iliosacral 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.

VI. Comparison of Technological Characteristics

The NextAR™ Spine System and the predicate NextAR™ Spine Platform, K223769, share the following characteristics:

- Intended use
- 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;

The subject NextAR™ Spine System differs from the predicate device with respect to:

- Rod planning feature
- Intra Operative Screw planning feature
- Fiducial Registration Accuracy

Discussion

The differences between the subject and the primary predicate device are concerning the rod planning and intra operative screw planning features.
They do not raise different questions of safety or effectiveness when compared to the predicate device. Both navigation systems utilize stereotaxic technologies.
Minor differences are addressed by performing cadaveric testing/ rational/ test.

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;
- Accuracy test
- performance testing
- cadaver study.

VIII. Conclusion

The information provided above supports that the NextAR™ Spine Platform is substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of design and technological characteristics, as well as performance evaluations. The NextAR™ Spine Platform can be considered substantially equivalent to the identified predicate devices.