May 5, 2023

NuVasive, Incorporated
Leah Andre
Regulatory Affairs Specialist
7475 Lusk Blvd
San Diego, California 92121

Re: K230989
Trade/Device Name: Rod Registration Frame
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 5, 2023
Received: April 6, 2023

Dear Leah Andre:

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,

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)*
K230989

Device Name
Rod Registration Frame

Indications for Use *(Describe)*
The surgical instruments are specifically designed for use with the Pulse System, which enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate.

When used with a Pulse Navigation system, the patient reference hardware is intended to provide a reference to a rigid anatomical structure that can be identified relative to the acquired image of the anatomy.

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."

510k Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.87, the following summary of information is provided:

A. Submitted by:

Leah Andre
Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (865) 724-9780
Date Prepared: April 5, 2023

B. Device Name

Trade or Proprietary Name:	*NuVasive® Rod Registration Frame*
Common Name:	Stereotaxic Instrument
Classification Name:	Stereotaxic Instrument
Device Class:	Class II
Regulation Number:	21 CFR § 888.4560
Product Code:	OLO

C. Predicate Devices

The subject NuVasive Rod Registration Frame is substantially equivalent to the primary predicate device NuVasive Spinous Process Clamp cleared in K210574. Additional reference device includes NuVasive Hip Pin (K210574).

D. Device Description

The subject NuVasive Rod Registration Frame is introducing modifications based on the design of existing patient reference hardware, the Spinous Process Clamp (Pulse System K210574). The Rod Registration Frame was designed to offer surgeons more flexibility during the registration process of Pulse Navigation by providing an additional patient reference hardware design option for attaching the existing Patient Reference Array to the patient. Despite the changes introduced to predicate Spinous Process Clamp (K210574), the subject device Rod Registration Frame is substantially equivalent to the predicate as demonstrated by verification and validation testing performed using well established and previously cleared test methods.

E. Indications for Use

The surgical instruments are specifically designed for use with the Pulse System, which enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate.

When used with a Pulse Navigation system, the patient reference hardware is intended to provide a reference to a rigid anatomical structure that can be identified relative to the acquired image of the anatomy.

F. Technological Comparison

The introduction of design change in patient fixation hardware introduces updated distal and proximal connection features and removal of radiographic markers (as the Rod Registration Frame is only used for non-fiducial registration).

The following table describes the summary comparison of technological characteristics of the subject device with the predicate devices:

Characteristics	Subject Device	K210574 Predicate Device	K210574 Reference Device
Indications for Use	The surgical instruments are specifically designed for use with the Pulse System, which enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate. When used with a Pulse Navigation system, the patient reference hardware is intended to provide a reference to a rigid anatomical structure that can be identified relative to the acquired image of the anatomy.	The surgical instruments are specifically designed for use with the Pulse System, which enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate. When used with a Pulse Navigation system, the patient reference hardware is intended to provide a reference to a rigid anatomical structure that can be identified relative to the acquired image of the anatomy.	The surgical instruments are specifically designed for use with the Pulse System, which enables computer-assisted navigation for spinal surgical procedures in which the use of stereotactic surgery may be appropriate. When used with a Pulse Navigation system, the patient reference hardware is intended to provide a reference to a rigid anatomical structure that can be identified relative to the acquired image of the anatomy.
Product Code	OLO	OLO	OLO
21 CFR Classification	§882.4560	§882.4560	§882.4560
Material	17-4 PH Stainless Steel conforming to ASTM A564	17-4 PH Stainless Steel and 465 Stainless Steel conforming to ASTM A564 and Nitronic 60 conforming to ASTM A267	316L SS per ASTM F138 and PPSU Radel R-5100
Principle of Operation	Patient reference hardware that provides a reference to a rigid anatomical structure.	Patient reference hardware that provides a reference to a rigid anatomical structure.	Patient reference hardware that provides a reference to a rigid anatomical structure.
Device Construct Design	• Patient reference hardware option for attaching Patient Reference Array to patient to acquire accurate patient registrations	• Patient reference hardware option for attaching Patient Reference Array to patient to acquire accurate patient	• Patient reference hardware option for attaching Patient Reference Array to patient to acquire accurate patient registrations

	needed for navigated surgery • Distal Connection Feature/Patient Fixation Method: Bent Rod component utilized for patient fixation by insertion through NuVasive pedicle screw systems • Proximal Connection Feature: Poker Chip component utilized for fixation to Extension Arm to facilitate connection to Patient Reference Array • No radiographic markers due to use of non-fiducial (Non-fiducial) registration only	registrations needed for navigated surgery • Distal Connection Feature/Patient Fixation Method: Clamp component utilized for patient fixation by actuating jaw features to clamp directly to spinous process • Proximal Connection Feature: PRA hub component utilized for fixation to Extension Arm with Articulating Adapter to facilitate connection to Patient Reference Array. Can also be attached directly to Patient Reference Array. • Radiographic markers used specifically for fiducial registration only	needed for navigated surgery • Distal Connection Feature/Patient Fixation Method: Sharp pin component utilized for patient fixation by fixation into pelvis • Proximal Connection Feature: PRA hub component utilized for fixation to Extension Arm with Articulating Adapter to facilitate connection to Patient Reference Array. Can also be attached directly to Patient Reference Array • May or may not have radiographic markers used specifically for fiducial registration only
Offered Lengths	Short and Long	Short and Long	Short and Long
Offered Diameters	Various; compatible with NuVasive Screw Systems	N/A	N/A
Registration Compatibility	Non-fiducial Registration	Fiducial and Non-fiducial Registration	Fiducial and Non-fiducial Registration
Method of Attachment	Inserted through NuVasive screw systems	Clamps directly to spinous process	Fixated into pelvis
Region of Anatomy	Cervical, Thoracic and Lumbar regions of the spine	Cervical, Thoracic and Lumbar regions of the spine	Lumbar and Sacral regions of the spine
Performance Data/ Testing/Analysis	• System Level Accuracy Testing • Cadaver Verification • Design Validation • Tolerance Analysis • Usability Validation	• System Level Accuracy Testing • Cadaver Verification • Design Validation • Tolerance Analysis • Usability Validation	• System Level Accuracy Testing • Cadaver Verification • Design Validation • Tolerance Analysis • Usability Validation
Accessory Instrumentation	Extension Arm which holds Patient Reference Array	Extension Arm with Articulating Adapter and/or Patient Reference Array	Extension Arm with Articulating Adapter and/or Patient Reference Array
Sterilization	Non-sterile Steam sterilization prior to use	Non-sterile Steam sterilization prior to use	Sterile (EO)

G. Performance Data

Non-clinical testing was performed using the same methodology and acceptance criteria as the previously cleared Spinous Process Clamp (K210574), demonstrating that the subject device's performance is substantially equivalent to the legally marketed predicate device. The following testing was performed:

- System Level Accuracy Testing

- Cadaver Verification
- Design Validation
- Tolerance Analysis
- Usability Validation

The results demonstrate that the subject Rod Registration Frame meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate. No clinical studies were conducted.

H. Conclusion

Results of non-clinical testing demonstrate that the subject device Rod Registration frame is substantially equivalent to the predicate device cleared in K210574.