December 2, 2020

NuVasive, Incorporated
Adan Alfaro
Regulatory Affairs Associate
7475 Lusk Blvd.
San Diego, California 92121

Re: K200719
Trade/Device Name: NuVasive Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 3, 2020
Received: November 4, 2020

Dear Adan Alfaro:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200719

Device Name
NuVasive Navigation.S Instruments

Indications for Use *(Describe)*
NuVasive Navigation.S Instruments are intended to be used during the preparation and placement of NuVasive screws (Reline, Reline C, and VuePoint fixation systems) and disc preparation during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.
The navigated disc preparation instruments are intended to be used to facilitate a discectomy or boney resection during spinal surgery. The navigated trials are intended to be used to facilitate implant size selection of NuVasive intervertebral body fusion devices during spinal surgery.
NuVasive Navigation.S Instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks 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."

510(k) Summary
In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Adan Alfaro
Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: December 1, 2020

B. Device Name

Trade or Proprietary Name:	NuVasive® Navigation.S Instruments
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Classification Name:	Stereotaxic instrument
Device Class:	Class II
Classification:	21 CFR § 882.4560
Product Code:	OLO

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device Navigated Anterolateral Disc Prep Instruments (K192336) and additional predicate device NuVasive Navigation Instruments (K172623).
Stimulation/Dissection Instruments (K112709) is being used as a reference predicate for materials and sterilization method of the subject sterile dilator.

D. Device Description

NuVasive Navigation.S Instruments are manual, non-sterile re-usable, or sterile single use surgical instruments intended for use with the Medtronic StealthStation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of NuVasive screws and preparation for placement of interbody implants during spinal surgery.

E. Indications for Use

NuVasive Navigation.S Instruments are intended to be used during the preparation and placement of NuVasive screws (Reline, Reline C, and VuePoint fixation systems) and disc preparation during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The navigated disc preparation instruments are intended to be used to facilitate a discectomy or boney resection during spinal surgery. The navigated trials are intended to be used to facilitate implant size selection of NuVasive intervertebral body fusion devices during spinal surgery.

NuVasive Navigation.S Instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

F. Comparison of Technological Characteristics with Predicate Device

As was established in this submission, the subject NuVasive Navigation.S Instruments are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject instruments are equivalent in dimensions when compared to Medtronic counterparts, utilize the same materials and sterilization method as predicate devices.

The subject device was shown to be substantially equivalent to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

Dimensional analysis of subject devices was provided to demonstrate they are equivalent in dimensions compared to Medtronic counterparts. Additionally, testing per *ASTM F2554 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical **Systems*** was performed. To demonstrate that the end-user can safely and effectively conduct the surgical workflows and the subject instruments will perform appropriately through the instrument verification process, compatibility testing for disc preparation instruments with Medtronic StealthStation was executed.

The results demonstrate that the subject NuVasive Navigation.S Instruments are substantially equivalent to the predicate.

H. Conclusions

The subject NuVasive Navigation.S Instruments have been shown to be substantially equivalent to legally marketed predicate devices for their intended use.