DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2017

NuVasive, Incorporated
Manthan Damani
Senior Regulatory Affairs Specialist
7475 Lusk Blvd.
San Diego, California 92121

Re: K172623
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 21, 2017
Received: November 22, 2017

Dear Manthan Damani:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K172623

Device Name
NuVasive® Navigation Instruments

Indications for Use *(Describe)*
NuVasive® Navigation Instruments are intended to be used during the preparation and placement of NuVasive screws (Armada, Reline, Precept, MAS PLIF, and VuePoint fixation systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. NuVasive® Navigation 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 a skull, a long bone, or 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.

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Food and Drug Administration
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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:

Manthan J. Damani
Senior Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: August 31, 2017

B. Device Name

Trade or Proprietary Name:	NuVasive® Navigation 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 Alphatec Spine Navigation Instruments (K153603). Additional predicate devices are Medtronic Navigated CD Horizon Solera Screwdriver and Taps (K140454), and Globus Navigation Instruments (K153203).

D. Device Description

NuVasive Navigation Instruments are manual, non-sterile, re-usable, surgical instruments intended for use with 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 during spinal surgery.

E. Indications for Use

NuVasive® Navigation Instruments are intended to be used during the preparation and placement of NuVasive screws (Armada, Reline, Precept, MAS PLIF, and VuePoint fixation systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. NuVasive® Navigation 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 a skull, a long bone, or 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 Instruments are substantially equivalent to other predicate devices cleared by the FDA for commercial

distribution in the United States. 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

Nonclinical testing was performed to demonstrate that the subject NuVasive® Navigation Instruments are substantially equivalent to the predicate device. The following testing was performed:

- Accuracy testing
- Compatibility testing
- Performance testing

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

H. Conclusions

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