NuVasive, Incorporated
Ms. Michelle Cheung
Sr. Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K180198
Trade/Device Name: NuVasive® VuePoint® II OCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: January 23, 2018
Received: January 24, 2018

Dear Ms. Cheung:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S for MNM

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)*

K180198

Device Name
NuVasive® VuePoint® II OCT System

Indications for Use *(Describe)*

The NuVasive® VuePoint® II OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The VuePoint II OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the VuePoint II OCT System may be connected to the NuVasive® SpheRx® Spinal System, Precept® Spinal System, Armada® Spinal System, Reline®System and Reline® 4.5-5.0 System via the rod to rod connectors or transition rods.

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:

Michelle Cheung
Senior Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3360

Date Prepared: January 23, 2018

B. Device Information

NuVasive® VuePoint® II OCT System
Orthosis, Cervical Pedicle Screw Spinal Fixation
Product Code: NKG
Unclassified, Pre-Amendment
Spinal interlaminar fixation
Regulation Number: § 888.3050
Product Code: KWP
Class II

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate *VuePoint II OCT System* (K150474), and additional predicates *VuePoint OCT System* (K093319), *Synthes SYNAPSE OCT System* (K142838), and Reline® System (K161014).

D. Device Description

The *NuVasive VuePoint II OCT System* consists of screws, hooks, rods, offset connectors, rod to rod connectors, set screws, cross connectors, occipital plates and associated general instruments. Implant components are available in a variety sizes and can be rigidly locked into a variety of configurations to suit the individual pathology and anatomical conditions of the patient. The scope of this submission includes the introduction of 5.0 and 5.5 mm diameter multi axial bone screws, sterile implants, as well as minor modifications to the implant design since clearance of reference device *NuVasive VuePoint II OCT System* (K150474).

E. Intended Use

The *NuVasive® VuePoint® II OCT System* is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The *VuePoint II OCT System* is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the *VuePoint II OCT System* may be connected to the *NuVasive® SpheRx® Spinal System, Precept® Spinal System, Armada® Spinal System, Reline® System* and *Reline® 4.5-5.0 System* via the rod to rod connectors or transition rods.

F. Technological Characteristics

The *NuVasive VuePoint II OCT System* is introducing a large diameter multi axial bone screw, sterile implants, and design modifications to components that have been modified since their clearance in reference device *VuePoint II OCT System* (K150474). Modifications include minor changes to multi axial, favoured angle, and occipital bone screws, additional rod lengths and intermediate rod diameters, lasermarking updates, and minor tolerance updates to improve manufacturability of existing implants. Overall, the subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, and packaging.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NuVasive VuePoint II OCT System* is substantially equivalent to the predicate device. The following testing was performed:

- Static and dynamic compression bending testing per ASTM F1717
- Static torsion testing per ASTM F1717
- Static tulip pull-off testing
- Static and Dynamic tulip shank interconnection strength testing per ASTM F1798

The results demonstrate that the subject *NuVasive VuePoint II OCT System* is substantially equivalent to the predicate.

H. Conclusions

The subject *NuVasive VuePoint II OCT System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.