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

January 7, 2016

NuVasive, Incorporated
Ms. Kelsey Lien
Senior Regulatory Affairs Coordinator
7475 Lusk Boulevard
San Diego, California 92121

Re: K153336
Trade/Device Name: Nuvasive® VuePoint® OCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: November 18, 2015
Received: November 19, 2015

Dear Ms. Lien:

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 yours,

Lori A. Wiggins -S

for
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K153336

Device Name
NuVasive® VuePoint® OCT System

Indications for Use *(Describe)*
The NuVasive® VuePoint® 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 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 OCT System may be connected to the NuVasive SpheRx® Spinal System, Precept® Spinal System, Armada® Spinal System and Reline™ 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.

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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:

Kelsey Lien
Senior Regulatory Affairs Coordinator
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: December 30, 2015

### B. Device Information

*NuVasive® VuePoint® 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 device *NuVasive® VuePoint® II OCT System* (K150474) and the reference device *NuVasive® VuePoint® OCT System* (K093319).

### D. Device Description

The *NuVasive® VuePoint® OCT System* is a occipito-cervico-thoracic posterior fixation system manufactured from Titanium alloy (Ti6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3 and Cobalt Chromium alloy conforming to ASTM F90 or ASTM F1537. The *NuVasive VuePoint OCT System* consists of screws, hooks, rods, offset 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 is to expand the indications for use of bone screws in the cervical (C1-C7) and thoracic (T1 to T3) spine.

**E. Indications for Use**

The *NuVasive VuePoint 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 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 OCT System* may be connected to the NuVasive SpheRx® Spinal System, Precept® Spinal System, Armada® Spinal System and Reline® System via the rod to rod connectors or transition rods.

**F. Technological Characteristics**

As was established in this submission, the subject *NuVasive VuePoint OCT System* is 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 and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, performance, material composition, and function.

**G. Performance Data**

The purpose of this 510(k) is to modify the Indications for Use for the subject *NuVasive VuePoint OCT System* to include the use of bone screws in the cervical spine and include the system's use with other NuVasive posterior pedicle screw systems, i.e., Precept Spinal System, Armada Spinal System and Reline System. No new *VuePoint OCT System* designs are being introduced to the previously cleared *VuePoint OCT System* (K093319) and only previously cleared devices are subject of this submission, i.e., there is no new worst case device. Mechanical performance testing data was provided for the original *VuePoint OCT System* in 510(k) K093319 to establish substantial equivalence. Since no new device designs and no new worst case sizes are being introduced to the *VuePoint OCT System*, the previously presented mechanical testing data in K093319 is sufficient to support the expanded indications for the *VuePoint OCT System.*

Additionally, a clinical literature review was performed to support the use of bone screws in treating conditions of the cervical (C1-C7) and upper thoracic (T1-T3).

**H. Conclusions**

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