



Food and Drug Administration
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Silver Spring, MD 20993-0002

NuVasive, Incorporated
Ms. Cynthia Adams
Regulatory Affairs Specialist
7475 Lusk Boulevard
San Diego, California 92121

October 21, 2015

Re: K150474
Trade/Device Name: NuVasive® VuePoint® II OCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: September 18, 2015
Received: September 21, 2015

Dear Ms. Adams:

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 Parts 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.

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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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150474

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 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.

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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:

Cynthia Adams
Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: October 19, 2015

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 *Medtronic Vertex Reconstruction System* (K143471) and additional predicates *Synthes Synapse Occipital-Cervical-Thoracic (OCT) System* (K142838) and *DePuy Mountaineer OCT Spinal System* (K151885). Reference devices include *VuePoint OCT System* (K093319), *OCT System* (K071435), and *Depuy Summit Occipito-Cervico-Thoracic (OCT) Spinal System* (K002733).

D. Device Description

The *NuVasive VuePoint II 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 includes indications for the use of bone screws in the cervical (C1-C7) and thoracic (T1 to T3) spine.

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 and Reline[™] System via the rod to rod connectors or transition rods.

F. Technological Characteristics

Unlike the reference device *VuePoint OCT System* (K093319), the *NuVasive VuePoint II OCT System* includes an adjustable occipital plate with variable screws, an adjustable offset rod-to-rod connector, adjustable cross connectors and a hinged rod. As was established in this submission, the subject *NuVasive VuePoint II OCT System* is substantially equivalent to the primary predicate *Medtronic Vertex Reconstruction System* (K143471) and additional predicate *DePuy Mountaineer OCT Spinal System* (K151885) for the use of pedicle and/or lateral mass screws in the cervical spine coupled to a rigid longitudinal element to achieve immobilization and stabilization of cervical spinal segments as an adjunct to fusion. 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, and function.

G. Performance Data

To establish substantial equivalence with predicate devices for the modified indications for use, a review of published literature was provided to support the use of bone screws in treating conditions of the cervical (C1-C7) and upper thoracic spine (T1-T3).

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 testing per ASTM F2706
- Static and dynamic torsion testing per ASTM F2706
- Static torsion testing per ASTM F1717
- Static axial rotation, lateral translation, and flexion bending 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.