

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:

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Date Prepared: June 14, 2010

B. Device Name

| | |
|----------------------------|---|
| Trade or Proprietary Name: | <i>NuVasive® VuePoint® OCT System</i> |
| Common or Usual Name: | Spinal Fixation Appliances |
| Classification Name: | Appliance, Fixation, Spinal Interlaminar and Spinal Pedicle Fixation Orthosis |
| Device Class: | Class II |
| Classification: | §888.3050 |
| Product Code: | KWP |

C. Predicate Devices

The subject *VuePoint OCT System* is substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K071435 – NuVasive OCT System
- K092287 – NuVasive SpheRx® II Pedicle Screw System
- K080828 – DePuy Spine™ MOUNTAINEER™ OCT Spinal System

D. Device Description

The *NuVasive VuePoint OCT System* consists of a variety of shapes and sizes of screws, rods, offset connectors, set screws, and cross connectors which can be rigidly locked in a variety of configurations to accommodate patient anatomy.

E. Intended Use

The *VuePoint® OCT System* is intended to promote fusion of the cervical spine and occipito-thoracic junction (Occiput-T3), and indicated for:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment,
3. Fracture/Dislocation,

4. Spinal Stenosis,
5. Atlantoaxial fracture with instability,
6. Occipitocervical dislocation,
7. Spinal tumor and/or
8. Revision of previous cervical spine surgery.

The occipital bone screws are limited to occipital fixation only.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The VuePoint OCT System can also be linked to the NuVasive SpheRx Spinal System via the rod to rod connectors or transition rods.

F. Technological Characteristics

As was established in this submission, the subject *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, material composition, function, and range of sizes.

G. Performance Data

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

- Static and dynamic torsion per ASTM draft standard WK455-Z9592Z
- Static and dynamic compression per ASTM draft standard WK455-Z9592Z
- Interconnection testing per ASTM F1798

The results of these studies showed that the subject *VuePoint OCT System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *VuePoint OCT System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 23 2010

NuVasive, Inc.
% Ms. Sheila Bruschi
Senior Regulatory Affairs Associate
7475 Lusk Boulevard
San Diego, California 92121

Re: K093319

Trade/Device Name: VuePoint® OCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: May 19, 2010
Received: May 20, 2010

Dear Ms. Bruschi:

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

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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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093319

Device Name: VuePoint® OCT System

Indications For Use:

The VuePoint® OCT System is intended to promote fusion of the cervical spine and occipito-thoracic junction (Occiput-T3), and is indicated for: (1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) Degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) Fracture/Dislocation, (4) Spinal Stenosis, (5) Atlantoaxial fracture with instability, (6) Occipitocervical dislocation, (7) Spinal tumor and/or (8) Revision of previous cervical spine surgery.

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Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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