


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:

Sheila Bruschi
 Associate Manager, Regulatory Affairs
 NuVasive, Incorporated
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SEP 11 2012

Date Prepared: September 11, 2012

B. Device Name

Trade or Proprietary Name:	<i>NuVasive® Precept™ Spinal System</i>
Common or Usual Name:	Pedicle Screw System
Classification Name:	Pedicle Screw Spinal System, Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation orthosis
Device Class:	Class III
Classification:	§888.3050, §888.3060, §888.3070
Product Code:	NKB, KWP, MNI, MNH, KWQ

C. Predicate Devices

The subject *NuVasive Precept Spinal System* is substantially equivalent to the *NuVasive Precept* (K102514) and *SpheRx® PPS* (K090981) Systems currently distributed commercially in the U.S. by NuVasive.

D. Device Description

The *NuVasive Precept Spinal System* consists of a variety of polyaxial screws, reduction screws, offset connectors, rods, locking nuts, and transverse connectors. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. This 510(k) is for the modification to a component used in the assembly of tulip to screw shanks of polyaxial screws. The system as a whole remains unchanged compared to the predicate (K102514).

E. Intended Use

When used as a pedicle screw fixation system, the *NuVasive Precept Spinal System* is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

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
4. Dislocation
5. Scoliosis



6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The *NuVasive® Precept™ Spinal System* is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the NuVasive Precept Spinal System is also intended for the following indications:

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. Spinal stenosis
3. Spondylolisthesis
4. Spinal deformities
5. Fracture
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Precept Spinal 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 *NuVasive Precept Spinal System* is substantially equivalent to other predicate devices. The following component testing was performed:

- Static and dynamic flexion-extension moment testing per ASTM F1798
- Tulip pull-off
- Tension-torsion
- Orbital Tension

The results of these studies showed that the system as a whole was unchanged compared to the predicate, and the subject *NuVasive Polyaxial Spinal Screws* meet or exceed the performance of the predicate devices, 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 *NuVasive Precept Spinal System* have 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

Nuvasive, Incorporated
% Ms. Sheila Bruschi
Associate Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

SEP 11 2012

Re: K122352

Trade/Device Name: NuVasive® Precept™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, MNI, MNH, KWQ
Dated: August 02, 2012
Received: August 03, 2012

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

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 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal line extending to the right.

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): K122352

Device Name: NuVasive® Precept™ Spinal System

Indications For Use:

When used as a pedicle screw fixation system, the NuVasive Precept Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

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6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

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

510(k) Number K122352