

APR 12 2004

NuVasive®, Incorporated

VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Laetitia Bernard
Manager of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
10065 Old Grove Road
San Diego, CA 92131
Telephone: (858) 527-1918
Date Prepared: November 11, 2003.

B. Device Name

Trade or Proprietary Name: *NuVasive Spinal System*
Common or Usual Name: Spinal Implants
Classification Name: Pedicle Screw Spinal System, Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation orthosis.

C. Predicate Devices

The subject device is substantially equivalent to similar previously cleared devices.

D. Device Description

The *NuVasive Spinal System* consists of a variety of polyaxial screws, fixed angle screws, 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.

E. Intended Use

When used as a pedicle screw fixation system, the NuVasive 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 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 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. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.

Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests

(Not Applicable).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NuVasive, Inc.
% Ms. Laetitia Cousin
7475 Lusk Boulevard
San Diego, California 92121

JUL 30 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K033546
Trade/Device Name: NuVasive Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWQ
Dated: January 22, 2004
Received: January 23, 2004

Dear Ms. Cousin:

This letter corrects our substantially equivalent letter of April 12, 2004.

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 (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.

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.

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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 (240) 276-3150 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 Melkerson". The signature is written in a cursive style with a large initial "M".

Mark Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K033546 -- 1 of 1

Device Name: NuVasive Spinal System

Indications for Use:

When used as a pedicle screw fixation system, the NuVasive 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).

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Mark N. McLean
Division Sign-Off
Division of General, Restorative,
and Neurological Devices

K 033546
510(k) Number

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR Over-The-Counter Use