5. 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 Cousin
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
4545 Towne Centre Court
San Diego, CA 92121
Telephone: (858) 909-1868
Date Prepared: May 22, 2007.

B. Device Name

Trade or Proprietary Name:	*NuVasive OCT System*
Common or Usual Name:	Spinal Fixation Appliances
Classification Name:	Appliance, Fixation, Spinal Interlaminal and Spinal Pedicle Fixation Orthosis

C. Predicate Devices

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

D. Device Description

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

E. Intended Use

When intended to promote fusion of the cervical spine and occipito-thoracic junction (Occiput-T3), the NuVasive OCT System 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.

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 NuVasive OCT System can also be linked to the NuVasive SpheRx Spinal System via the rod to rod connectors.

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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2007

NuVasive, Incorporated
% Ms. Laetitia Cousin
Director of Regulatory Affairs
and Quality Assurance
4545 Towne Centre Court
San Diego, CA 92121

Re: K071435
Trade/Device Name: NuVasive OCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI
Dated: May 22, 2007
Received: May 23, 2007

Dear Ms. Laetitia Cousin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: *NuVasive OCT System*

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-thoracic junction (Occiput-T3), the NuVasive OCT System 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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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071435

Prescription Use X (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)