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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 Cousin
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
4545 Towne Centre Court
San Diego, CA 92121
Telephone: (858) 909-1868
Date Prepared: February 1, 2005.

B. Device Name

Trade or Proprietary Name:	*NuVasive CoRoent System*
Common or Usual Name:	Vertebral Body Replacement Device
Classification Name:	Vertebral Body Replacement Device

C. Predicate Devices

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

D. Device Description

The *NuVasive CoRoent System* is an implantable PEEK vertebral body replacement device indicated for use in the thoracic and lumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of a collapsed, damaged, or unstable vertebral body(s) due to tumor or trauma and to achieve decompression of the spinal cord and neural tissues.

The device is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

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E. Intended Use

The NuVasive CoRoent System is a partial vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of a collapsed, damaged, or unstable vertebral body(s) due to tumor or trauma and to achieve decompression of the spinal cord and neural tissues. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

F. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to the following predicate devices:

K033517	Spinal Concepts Cadence™	Spinal concepts, Inc.
K011037	Vertebral Spacer	Synthes
K032476	NuVasive Mesh	NuVasive, Inc.
K041939	Blackstone VBR System	Blackstone Medical, Inc.

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

FEB - 7 2005

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

Re: K043405
Trade/Device Name: NuVasive CoRoent System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 9, 2004
Received: December 10, 2004

Dear Ms. 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" (21 CFR 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K043405

Device Name: *NuVasive CoRoent System*

Indications for Use:

The NuVasive CoRoent System is a partial vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of a collapsed, damaged, or unstable vertebral body(s) due to tumor or trauma and to achieve decompression of the spinal cord and neural tissues. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043405

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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