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VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Laetitia Bernard
Manager of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
10065 Old Grove Road
San Diego, California 92131
Telephone: (858) 527-1918
Telefacsimile: (858) 271-7101

B. Device Name

Trade Name: NuVasive Mesh

Common or Usual Name: Vertebral Body Replacement Device

Classification Name: Vertebral Body Replacement Device

C. Predicate Devices

The subject NuVasive Mesh is substantially equivalent to the *NuVasive Mesh* currently manufactured and distributed commercially in the U.S. by NuVasive, Inc.

D. Device Description

The *NuVasive Mesh* is an implantable titanium 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 tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

A plurality of rhombic pattern holes are built in the wall, transverse to the longitudinal axis. The hollow core allows for packing of bone grafting materials to help promote a solid fusion. A ring of small spikes or teeth on each end of the device serves to grip the endplates of the adjacent vertebrae to resist expulsion.

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 Mesh is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive® Mesh 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 current NuVasive Mesh 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.

Due to this equivalency, the device raises no new safety or effectiveness issues.

G. Summary of Design Control Activities

Design control activities employed to control the development of the modification to the NuVasive Mesh included:

- a comprehensive Risk Analysis to identify potential risks and failures associated with operation of the device, any mitigations incorporated to reduce or eliminate those risks and failures, and an assessment of residual risk;
- a comprehensive program of verification and validation activities demonstrating that acceptance criteria were met, and that design output satisfied design input.

H. Summary of Clinical Tests

(Not applicable.)

H. Summary of Non-Clinical Tests

Mechanical testing was presented.

J. Conclusions

The subject device is substantially equivalent to the currently marketed predicate device, and its development has been adequately and appropriately conducted and validated under a comprehensive design control program complying with Title 21 CFR, §820.30.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Ms. Laetitia Bernard
Manager of Regulatory Affairs & Quality Assurance
NuVasive, Incorporated
10065 Old Grove Road
San Diego, California 92131

Re: K032476
Trade/Device Name: NuVasive Mesh
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: October 31, 2003
Received: November 3, 2003

Dear Ms. Bernard:

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.

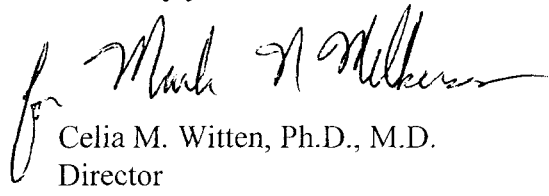
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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/dsma/dsmamain.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

D. Indications for Use Statement

510(k) Number (if known): K032476

Device Name: *NuVasive Mesh*

Indications for Use:

The NuVasive® Mesh is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive® Mesh 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

Mark N Milhous

(Division Sign-
Division of Ge restorative
and Neurologi ices

510(k) Numbe: K032476