

**5. 510(k) SUMMARY**

**MAR 28 2008**

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 and Clinical Affairs, and Quality Assurance  
NuVasive, Incorporated  
4545 Towne Centre Court  
San Diego, California 92121  
Telephone: (858) 909-1868  
Fax: (858) 909-2068

**B. Device Name**

Trade or Proprietary Name: *NuVasive® Spinous Process Plate System*  
Common or Usual Name: Spinal Implants  
Classification Name: Spinal Interlaminar Fixation Orthosis.  
Device Class: Class II  
Classification: §888.3050  
Product Code: KWP

**C. Predicate Devices**

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

**D. Device Description**

The *NuVasive® Spinous Process Plate System* features plates with spikes under the plate to help resist plate rotation after implantation.

**E. Intended Use**

The *NuVasive® Spinous Process Plate System* is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. It is not intended for stand-alone use.

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***F. Substantial Equivalence***

Data was provided which demonstrated the *NuVasive® Spinous Process Plate System* to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material, and function.

***G. Summary of Non-Clinical Tests***

Mechanical testing was presented.

***H. Summary of Clinical Tests***

(Not Applicable).

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 28 2008**

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

Re: K073278  
Trade/Device Name: NuVasive® Spinous Process Plate System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: KWP  
Dated: March 5, 2008  
Received: March 6, 2008

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.

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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): K073278

Device Name: NuVasive® Spinous Process Plate System

Indications for Use:

The *NuVasive® Spinous Process Plate System* is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. It is not intended for stand-alone use.

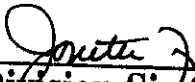
Prescription Use    
(Part 21 CFR 801 Subpart D)

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 General, Restorative,  
and Neurological Devices

510(k) Number K073278

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