

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 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 CoRoent System*
Common or Usual Name: Spinal Implants
Classification Name: Orthosis, spinal intervertebral fusion
Device Class: Class II
Classification: §888.3080
Product Code: ODP

C. Predicate Devices

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

D. Device Description

The *NuVasive CoRoent System* is an implantable device manufactured from PEEK and titanium alloy that is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

E. Intended Use***Intervertebral Body Fusion***

The NuVasive CoRoent System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion.

The CoRoent L and XL platforms are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

The CoRoent S platforms are intended for use for anterior cervical interbody fusion in patients with cervical degenerative disc disease (DDD) at one level from levels C2-C3 to C7- T1. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment. The System is intended to be used with supplemental fixation and autogenous bone graft only to facilitate the fusion.

Partial Vertebral Body Replacement

The NuVasive CoRoent System may also be used as a partial 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 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. Substantial Equivalence

Data was provided which demonstrated the *NuVasive CoRoent 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).



OCT - 2 2008

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

Re: K081611
Trade/Device Name: NuVasive CoRoent System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 26, 2008
Received: September 29, 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. 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Indications for Use

Mark H. Melburn

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number (if known): K081611

Device Name: NuVasive CoRoent System

510(k) Number K081611

Indications for Use:

Intervertebral Body Fusion

The NuVasive CoRoent System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion.

The CoRoent L and XL platforms are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

The CoRoent S platforms are intended for use for anterior cervical interbody fusion in patients with cervical degenerative disc disease (DDD) at one level from levels C2-C3 to C7- T1. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment. The System is intended to be used with supplemental fixation and autogenous bone graft only to facilitate the fusion.

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The NuVasive CoRoent System may also be used as a partial 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 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.

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)