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**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, California 92121  
Telephone: (858) 909-1868  
Fax: (858) 909-2068

DEC 04 2007

**B. Device Name**

Trade or Proprietary Name: *NuVasive CoRoent System*  
Common or Usual Name: Spinal Implants  
Classification Name: Intervertebral Body Fusion Device; Spinal Intervertebral Body Fixation Orthosis.  
Device Class: Class II  
Classification: §888.3080 and §888.3060  
Product Code: MAX, MQP

**C. Predicate Devices**

The subject device is substantially equivalent to RSB's InterFix device cleared under K071922.

**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.

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***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).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 04 2007

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

Re: K071795  
Trade/Device Name: *NuVasive CoRoent® System*  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX, MQP  
Dated: November 19, 2007  
Received: November 21, 2007

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.

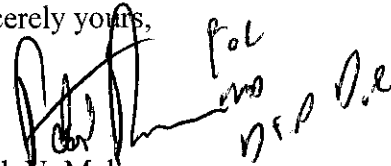
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

## Indications for Use

510(k) Number (if known): K071795

Device Name: CoRoent® System

Indications For Use:

### ***Intervertebral Body Fusion***

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### ***Partial Vertebral Body Replacement***

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Prescription Use    
 (Part 21 CFR 801 Subpart D)

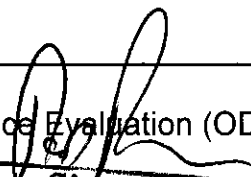
AND/OR

Over-The-Counter Use    
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

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Division of General, Restorative,  
and Neurological Devices

510(k) Number K071795