



Food and Drug Administration  
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April 20, 2016

NuVasive, Incorporated  
Ms. Michelle Cheung  
Associate, Regulatory Affairs  
7475 Lusk Boulevard  
San Diego, California 92121

Re: K160051

Trade/Device Name: NuVasive® Interfixated Interbody System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD  
Dated: March 23, 2016  
Received: March 23, 2016

Dear Ms. Cheung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Lori A. Wiggins -S

for  
Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160051

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Device Name

NuVasive® Interfixated Interbody System

Indications for Use (Describe)

The NuVasive® Interfixated Interbody System is indicated for the following:

**CoRoent XL-F System**

The *NuVasive CoRoent XL-F 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 and supplemental internal spinal fixation systems (e.g., pedicle or facet screws) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *CoRoent XL-F System* is intended for use in interbody fusions in the lumbar spine from L2 to L5, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) with up to Grade I spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The *CoRoent XL-F System* implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

**Brigade System**

The *Brigade System* is indicated for spinal fusion procedures in skeletally mature patients. The *Brigade Standalone System* (lordotic angles of 8° and 12°) is a standalone system. The *Brigade Hyperlordotic System* (lordotic angles of 15° to 30°) must be used with supplemental internal spinal fixation systems (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous bone graft to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *Brigade System* is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) with up to Grade I spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The *Brigade System* implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis, and when used in these patients at multiple levels, the *Brigade Standalone System* must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**



## 510(k) Summary

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

### A. Submitted by:

Michelle Cheung, Esq.  
Associate, Regulatory Affairs  
NuVasive, Incorporated  
7475 Lusk Blvd.  
San Diego, California 92121  
Telephone: (858) 909-3360

Date Prepared: January 8, 2016

### B. Device Name

|                            |  |
|----------------------------|--|
| Trade or Proprietary Name: | <i>NuVasive® Interfixated Interbody System</i> |
| Common or Usual Name:      | Intervertebral Body Fusion Device              |
| Classification Name:       | Intervertebral Body Fusion Device              |

|                 |                   |
|-----------------|-------------------|
| Device Class:   | Class II          |
| Classification: | 21 CFR § 888.3080 |
| Product Code:   | OVD               |

### C. Predicate Devices

The subject *NuVasive Interfixated Interbody System* is substantially equivalent to primary predicate *NuVasive CoRoent XL-F System* (K140479), and additional predicates *NuVasive CoRoent Single Tab System* (K131723), *CoRoent XLR Standalone System* (K100043), *Brigade Hyperlordotic System* (K123045), and *CoRoent Thoracolumbar System* (K153419).

### D. Device Description

The subject *NuVasive Interfixated Interbody System* are interbodies manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026 PEEK-Optima® LT-1, with radiographic markers manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The devices all contain integrated screws made of titanium alloy, and include a hollow core or graft aperture which allows for packing of autograft to help promote a solid fusion. The subject implants contain small spikes or teeth on each end of the device which serve to grip the adjacent vertebrae to resist migration and expulsion.

The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. In addition to the integrated screws, the *CoRoent XL-F System* and *Brigade Hyperlordotic System* devices are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.



## **E. Intended Use**

The *NuVasive® Interfixated Interbody System* is indicated for the following:

### ***CoRoent XL-F System:***

The *NuVasive CoRoent XL-F 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 and supplemental internal spinal fixation systems (e.g., pedicle or facet screws) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *CoRoent XL-F System* is intended for use in interbody fusions in the lumbar spine from L2 to L5, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) with up to Grade I spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. *The CoRoent XL-F System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.*

### ***Brigade System:***

The *Brigade System* is indicated for spinal fusion procedures in skeletally mature patients. *The Brigade Standalone System* (lordotic angles of 8° and 12°) is a standalone system. *The Brigade Hyperlordotic System* (lordotic angles of 15° to 30°) must be used with supplemental internal spinal fixation systems (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous bone graft to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *Brigade System* is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) with up to Grade I spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. *The Brigade System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis, and when used in these patients at multiple levels, the Brigade Standalone System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.*

## **F. Technological Characteristics**

As was established in this submission, the subject *Interfixated Interbody System* is substantially equivalent to predicate device systems already cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.

**G. Performance Data**

No new device designs for the *CoRoent XL-F System* and no new worst case sizes for the *Brigade System* are being introduced to the subject *Interfixated Interbody System*. Therefore, no performance testing was performed for this 510(k) submission.

A retrospective clinical analysis was performed to support the use of the subject device as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

**H. Conclusions**

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *Interfixated Interbody System* has been shown to be substantially equivalent to legally marketed predicate devices, and as safe and as effective for its intended use.