



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

April 13, 2016

Re: K153419

Trade/Device Name: NuVasive® CoRoent® Thoracolumbar System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: March 18, 2016
Received: March 21, 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,

Vincent J. Devlin -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)
K153419

Device Name
NuVasive® CoRoent® Thoracolumbar System

Indications for Use (Describe)

The NuVasive CoRoent Thoracolumbar 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 cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The CoRoent Thoracolumbar System (XL platform) implants are intended for use in interbody fusions at one or two contiguous levels in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic disc degeneration (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain). The CoRoent Thoracolumbar System (XL and L platforms) implants are intended for use at one or two contiguous levels in the lumbar spine, from L1 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 CoRoent Thoracolumbar System (XL and L platforms) implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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.

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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: April 12, 2016

B. Device Name

Trade or Proprietary Name: *NuVasive[®] CoRoent[®] Thoracolumbar System*
Common or Usual Name: Intervertebral Body Fusion Device
Classification Name: Spinal Intervertebral Body Fixation orthosis

Device Class: Class II
Classification: 21 CFR § 888.3080
Product Code: MAX, PHM

C. Predicate Devices

The subject *NuVasive CoRoent Thoracolumbar System* is substantially equivalent to primary predicate *CoRoent Lumbar System* (K151472), and additional predicate *CoRoent Thoracolumbar Implants* (K150994).

D. Device Description

The subject *NuVasive CoRoent Thoracolumbar System* are interbodies manufactured from PEEK-Optima[®] LT-1 conforming to ASTM F2026 or titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The PEEK devices contain titanium alloy radiographic markers conforming to ASTM F136 or ASTM F1472 or tantalum markers conforming to ASTM 560 or ISO 13782. The device's hollow core or graft aperture allows for packing of autograft to help promote a solid fusion. Small spikes or teeth on each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device.

The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. The device is 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 CoRoent Thoracolumbar 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 cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The CoRoent Thoracolumbar System (XL platform) implants are intended for use in interbody fusions at one or two contiguous levels in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic disc degeneration (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain). The CoRoent Thoracolumbar System (XL and L platforms) implants are intended for use at one or two contiguous levels in the lumbar spine, from L1 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 CoRoent Thoracolumbar System (XL and L platforms) implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

F. Technological Characteristics

As was established in this submission, the subject *CoRoent Thoracolumbar 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 and no new worst case sizes are being introduced to the subject *CoRoent Thoracolumbar System*. Therefore, no performance testing was performed for this 510(k) submission.

A clinical literature review 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 *CoRoent Thoracolumbar System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.