DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 26, 2017

NuVasive, Incorporated
Marysa Loustalot
Sr. Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K170962
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 30, 2017
Received: March 31, 2017

Dear Marysa Loustalot:

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 Part 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" (21 CFR 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
170962

K170962
Page 1 of 1

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 and/or allogeneic bone graft comprised of cancellous and/or corticocancellous 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 NuVasive CoRoent Thoracolumbar System (XL platform) implants are intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and the CoRoent Thoracolumbar System (XL and L platforms) implants are intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The NuVasive CoRoent Thoracolumbar System (XL and L platforms) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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

Marysa Loustalot
Sr. Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: June 22, 2017

B. Device Name

Trade or Proprietary Name:	*NuVasive® CoRoent® Thoracolumbar System*
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:	MAX, PHM

C. Predicate Devices

The subject *NuVasive CoRoent Thoracolumbar System* is substantially equivalent to the primary predicate device, *NuVasive Lumbar Interbody Implants* (K161230), and additional predicates *NuVasive CoRoent Thoracolumbar System* (K153419) and *NuVasive CoRoent Titanium System* (K120918).

D. Device Description

The subject *NuVasive CoRoent Thoracolumbar System* consists of devices manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3, and PEEK Optima LT-1 with titanium alloy or tantalum pins conforming to ASTM F136 or ASTM F1472 (tantalum markers conforming to ASTM 560 or ISO 13782). The implants are hollow devices with teeth on the endplate surfaces. The hollow core allows for the packing of autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to help promote a solid fusion. Small teeth on each end of the device serve to grip the adjacent vertebrae to resist migration of the device. The varying footprints are designed to address individual pathology and anatomic conditions of the patient, utilizing placement through various surgical approaches. The device is intended to be used with supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The subject implants are offered sterile and non-sterile with the accessory surgical instruments packaged as non-sterile to be sterilized by the end user.

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The purpose of this 510(k) submission is to introduce titanium versions of the PEEK devices cleared in K161230 and add MR Conditional labeling.

E. Indications for 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 and/or allogeneic bone graft comprised of cancellous and/or corticocancellous 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 *NuVasive CoRoent Thoracolumbar System* (XL platform) implants are intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and the *CoRoent Thoracolumbar System* (XL and L platforms) implants are intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The *NuVasive CoRoent Thoracolumbar System* (XL and L platforms) 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 *NuVasive CoRoent Thoracolumbar System* is substantially equivalent to other predicate devices 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

Mechanical performance testing data was provided as part of the previous submissions to establish substantial equivalence for their use. The previously presented mechanical testing data are sufficient to support the addition of the titanium alloy implants to the subject system and does not warrant the need for additional nonclinical testing. Therefore, no new mechanical testing was performed for this 510(k) submission.

Additionally, an engineering rationale was provided for MR compatibility for subject devices.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *NuVasive CoRoent Thoracolumbar System* has been shown to be substantially equivalent to legally marketed predicate devices.