DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 25, 2016

NuVasive, Incorporated
Martin Yahiro, M.D.
Director, Medical Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K161230
Trade/Device Name: NuVasive® Lumbar Interbody Implants
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: July 25, 2016
Received: July 26, 2016

Dear Dr. Yahiro:

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,

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)*
K161230

Device Name
NuVasive® Lumbar Interbody Implants

Indications for Use *(Describe)*

NuVasive® Lumbar Non-Interfixated Interbody Implants:

The NuVasive Lumbar Interbody Implants are 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 Lumbar Interbody Implants (XL platform) are intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and the Lumbar Interbody Implants (XL and L platforms) 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 Lumbar Interbody Implants (XL and L platforms) are also indicated for use in the treatment of multilevel degenerative scoliosis in the thoracolumbar spine.

NuVasive® Lumbar Interfixated Interbody Implants:

CoRoent XL-F System:
The NuVasive Lumbar Interbody Implants (CoRoent XL-F platform) are 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 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. The devices are to be used in patients who have had at least six months of non-operative treatment.
The CoRoent XL-F platform implants are 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) or degenerative 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 platform implants can also be used as an adjunct for fusion in patients diagnosed with multilevel degenerative scoliosis.

Brigade System:
The NuVasive Lumbar Interbody Implants (Brigade System platform) are 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., posterior pedicle screw and rod 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 and/or allogeneic 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 Lumbar Interbody Implants (Brigade System platform) are 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) or degenerative 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 platform implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis. However, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the Brigade System platform 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.

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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:

Martin Yahiro, M.D.
Director, Medical Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 638-5589

Date Prepared: August 22, 2016

B. Device Name

Trade or Proprietary Name:	*NuVasive® Lumbar Interbody Implants*
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, OVD

C. Predicate Devices

The subject *NuVasive Lumbar Interbody Implants* is substantially equivalent to the primary predicate device, the *NuVasive® Lumbar Interbody Implants* (K153782), *NuVasive CoRoent System* (K141896), *NuVasive CoRoent Thoracolumbar System* (K153419), and *NuVasive Interfixated Interbody System* (K160051).

D. Device Description

The subject *NuVasive Lumbar Interbody Implants* are interbody implants manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026. Additinally, *CoRoent Ti-C* implants are PEEK devices with a commercially pure titanium (CP Ti) coating applied to the superior and inferior surfaces of the device. 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 graft material 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 interfixated version of the subject *NuVasive Lumbar Interbody Implants* devices are composed of an interbody device manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026, MP35N conforming to ASTM F562, and titanium alloy conforming to ASTM F136 and ISO 5832-3. The *Lumbar Interfixated Interbody System* implants have four screw holes in the anterior wall of the PEEK implant that allow titanium alloy screws to be placed in the cranial and caudal vertebral bodies or one or two integrated tabs to allow a titanium

alloy screw to be placed in the cranial and caudal vertebral bodies. Additionally, implants include titanium alloy radiographic markers conforming to industry recognized standards.

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 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

NuVasive® Lumbar Non-Interfixated Interbody Implants:

The *NuVasive Lumbar Interbody Implants* are 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 *Lumbar Interbody Implants* (XL platform) are intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and the *Lumbar Interbody Implants* (XL and L platforms) 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 *Lumbar Interbody Implants* (XL and L platforms) are also indicated for use in the treatment of multilevel degenerative scoliosis in the thoracolumbar spine.

NuVasive® Lumbar Interfixated Interbody Implants:

CoRoent XL-F System:

The *NuVasive Lumbar Interbody Implants* (*CoRoent XL-F* platform) are 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 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. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *CoRoent XL-F* platform implants are 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) or degenerative 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* platform implants can also be used as an adjunct for fusion in patients diagnosed with multilevel degenerative scoliosis.

Brigade System:

The *NuVasive Lumbar Interbody Implants* (*Brigade System* platform) are 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., posterior pedicle screw and rod 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 and/or allogeneic 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 *Lumbar Interbody Implants* (*Brigade System* platform) are 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) or degenerative 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* platform implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis. However, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the *Brigade System* platform 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 *NuVasive Lumbar Interbody Implants* 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 in the lumbosacral spine when used with autogenous bone graft: worst case devices included with the subject system were tested and cleared in these predicate 510(k) submissions. The proposed expansion of the indications for use to include their use in the treatment of lumbar spondylolisthesis does not create a new mechanical worst-case for any of the implants. Since no new device designs and no new worst case sizes are being introduced to the subject *NuVasive Lumbar Interbody Implants*, the previously presented mechanical testing data are sufficient to support the proposed use of allograft with 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.

A retrospective clinical analysis was performed to support the use of the subject device as am adjunct to fusion in patients diagnosed with lumbar spondylolisthesis. Based on the published clinical literature review, it was determined that the *NuVasive Lumbar Interbody Implants* used in the treatment of lumbar spondylolisthesis has a safety and effectiveness profile that is similar to the predicate devices.

The subject *NuVasive Lumbar Interbody Implants* meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate. No clinical studies were conducted.

H. Conclusions

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