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

April 23, 2015

NuVasive, Incorporated
Ms. Olga Lewis
Regulatory Affairs Specialist
7475 Lusk Boulevard
San Diego, California 92121

Re: K143684
Trade/Device Name: NuVasive® Reline™ System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: March 24, 2015
Received: March 25, 2015

Dear Ms. Lewis:

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 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

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)*
K143684

Device Name
NuVasive® Reline™ System

Indications for Use *(Describe)*
When used as a pedicle screw fixation system, the NuVasive Reline System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:
1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

When used for posterior non-cervical screw fixation in pediatric patients, NuVasive Reline System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the NuVasive Reline System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

The NuVasive Reline System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the NuVasive Reline System is also intended for the following indications:
1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Spinal stenosis
3. Spondylolisthesis
4. Spinal deformities
5. Fracture
6. Pseudoarthosis
7. Tumor resection and/or
8. Failed previous fusion

In order to achieve additional levels of fixation, the Reline System rods may be connected to the Armada System.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

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

Date Prepared: December 23, 2014

B. Device Name

Trade or Proprietary Name:	*NuVasive® Reline™ System*
Common or Usual Name:	Pedicle Screw System
Classification Name:	Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis
Device Class:	Class III
Classification:	21 CFR § 888.3050, 888.3060, 888.3070
Product Code:	NKB, OSH, MNI, MNH, KWQ,KWP

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device *Reline System* (K142499) and additional predicate devices, *GSB Global Balance System* (K132014), *SpheRx II Pedicle Screw System* (K091502), *Synthes USS Universal Spine System* (K111358), and *Medtronic CD HORIZON Spinal System* (K141604).

D. Device Description

The *NuVasive Reline System* is a pedicle screw system that consists of a variety screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors, iliac connectors and associated general instruments. Implant components are available in a variety sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. This 510(k) is to add new components to the *Reline System*.

E. Intended Use

When used as a pedicle screw fixation system, the *NuVasive Reline System* is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture

4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

When used for posterior non-cervical screw fixation in pediatric patients, *NuVasive Reline System* implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the *NuVasive Reline System* is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

The *NuVasive Reline System* is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the *NuVasive Reline System* is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Spinal stenosis
3. Spondylolisthesis
4. Spinal deformities
5. Fracture
6. Pseudoarthosis
7. Tumor resection and/or
8. Failed previous fusion

In order to achieve additional levels of fixation, the *Reline System* rods may be connected to the *Armada System*.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Reline 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 equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NuVasive Reline System* is substantially equivalent to the predicate device. The following testing was performed:

- Dynamic Compression Bending per ASTM F1717
- Static Axial Slip per ASTM F1798
- Static and Dynamic Flexion –Extension moment per ASTM F1798
- Static Tulip Pull-off

The results demonstrate that the subject *NuVasive Reline System* is substantially equivalent to the predicate.

H. Conclusions

The subject *NuVasive Reline System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.