January 11, 2023

NuVasive, Incorporated
Bland Tanesha
Sr. Regulatory Affairs Specialist
7475 Lusk Blvd
San Diego, California 92121

Re: K223181
Trade/Device Name: NuVasive Reline System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: October 10, 2022
Received: October 11, 2022

Dear Bland Tanesha:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223181

Device Name
NuVasive Reline System

Indications for Use *(Describe)*
When used as a pedicle screw fixation system in skeletally mature patients, the NuVasive Reline System is intended to provide immobilization and stabilization of spinal segments 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)

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. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

When used for posterior non-cervical screw fixation in pediatric patients, NuVasive Reline System is indicated as an adjunct to fusion to treat:
1. adolescent idiopathic scoliosis.
2. progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis,
3. spondylolisthesis,
4. spondylolysis,
5. pseudarthrosis,
6. failed prior fusion and
7. fracture caused by tumor and/or trauma in pediatric patients.
Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

In order to achieve additional levels of fixation, the NuVasive 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)

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:

Tanesha Bland
Sr. Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (323)683-5714

Date Prepared: October 10, 2022

B. Device Name

Trade or Proprietary Name:	*NuVasive Reline System*
Common or Usual Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral pedicle screw system
Device Class:	Class II
Classification:	21 CFR § 888.3070
Product Code:	NKB, KWP, KWQ

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device *CD Horizon™ Spinal System* (K211958) and additional predicate devices, *NuVasive Reline 4.5-5.0 System* (K190636) *and GSB Global Spinal Balance System* (K132014).

D. Device Description

The *NuVasive Reline System* is a pedicle screw system that consists of a variety of screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors, iliac connectors and associated general instruments. Implant components are available in a variety of sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. The purpose of this submission is to introduce "Dual-Headed Modular Connectors" which will be included in the NuVasive Reline System. Additionally, this submission is intended to specify pediatric progressive deformities in the indications for use statement for NuVasive Reline System. Lastly, this submission is intended to add minor labeling changes to address compatibility updates to the NuVasive Reline system.

E. Indications for Use

When used as a pedicle screw fixation system in skeletally mature patients, the *NuVasive Reline System* is intended to provide immobilization and stabilization of spinal segments 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)

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. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

When used for posterior non-cervical screw fixation in pediatric patients, *NuVasive Reline System* is indicated as an adjunct to fusion to treat:

1. adolescent idiopathic scoliosis.
2. progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis,
3. spondylolisthesis,
4. spondylolysis,
5. pseudarthrosis,
6. failed prior fusion and
7. fracture caused by tumor and/or trauma in pediatric patients.

Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

In order to achieve additional levels of fixation, the *NuVasive 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:

- Static Compression Bending Testing per ASTM F1717-21
- Dynamic Compression Bending Testing per ASTM F1717-21

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.