NuVasive, Incorporated
Sali Gully
Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

February 23, 2022

Re: K213654
Trade/Device Name: NuVasive® Reline® Cervical System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: February 17, 2022
Received: February 18, 2022

Dear Ms. Gully:

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,

for

Colin O’Neil, 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)*

K213654

Device Name
NuVasive® Reline® Cervical System

Indications for Use *(Describe)*

The NuVasive Reline Cervical System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Reline Cervical System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Reline Cervical System may be connected to the NuVasive SpheRx Spinal System, Precept Spinal System, Armada Spinal System, Reline System and Reline 4.5-5.0 System via the rod to rod connectors or transition rods.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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:

Sali Gully
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3360

Date Prepared: February 22, 2022

B. Device Information

Trade or Proprietary Name:	*NuVasive® Reline® Cervical System*
Common Name:	Cervical Pedicle Screw Spinal Fixation
Classification Name:	Spinal Interlaminal Fixation Orthosis Posterior Cervical Screw System
Regulation Number:	21 CFR § 888.3050, 21 CFR § 888.3075
Product Code:	KWP, NKG

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate Reline Cervical System (K191553) and additional predicates *VuePoint II OCT System* (K180198), and *VuePoint OCT System* (K093319).

D. Device Description

The *NuVasive Reline Cervical System* is an occipito-cervico-thoracic posterior system manufactured from Titanium alloy (Ti6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3 and Cobalt Chromium alloy conforming to ASTM F90 or ASTM F1537. The *Reline Cervical System* consists of a variety of components including screws, rods, offset connectors, rod to rod connectors, set screws, cross connectors, hooks, eyelets, and occipital plates which can be rigidly locked in a variety of configurations to accommodate patient anatomy.

E. Intended Use

The *NuVasive Reline Cervical System* is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The *Reline Cervical System* is also

intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the *Reline® Cervical System* may be connected to the *NuVasive® SpheRx® Spinal System, Precept® Spinal System, Armada® Spinal System, Reline® System* and *Reline® 4.5-5.0 System* via the rod to rod connectors or transition rods.

F. Technological Characteristics

The subject *NuVasive Reline Cervical System* is an occipito-cervico-thoracic posterior system manufactured from Titanium alloy (Ti6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3 and Cobalt Chromium alloy conforming to ASTM F90 or ASTM F1537. The *Reline Cervical System* consists of a variety of components including screws, hooks, rods, lock screws, transverse crosslinks, rod connectors, occipital plates, and occipital screws which can be rigidly locked in a variety of configurations to accommodate patient anatomy. Overall, the subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, and packaging.

G. Performance Data

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

- Dynamic Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Static My per ASTM F1798
- Static Fz per ASTM F1798

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

H. Conclusions

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