November 3, 2021

NuVasive, Incorporated
Priscila Saraiva
Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K212446
Trade/Device Name: NuVasive® Anterior Cervical Plate Systems
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 4, 2021
Received: August 5, 2021

Dear Priscila Saraiva:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212446

Device Name
NuVasive® ACP System

Indications for Use *(Describe)*

The NuVasive® ACP System is intended for anterior screw fixation of the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212446

Device Name
NuVasive Archon® Anterior Cervical Plate System

Indications for Use *(Describe)*

The NuVasive Archon Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of. the implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion. Additionally, the three-hale version of the implant system may be appropriate only for patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.

WARNING: The NuVasive Archon Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212446

Device Name
NuVasive® SmartPlate Gradient Plus System

Indications for Use *(Describe)*

The NuVasive SmartPlate Gradient Plus System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive SmartPlate Gradient Plus System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212446

Device Name
NuVasive® HELIX Anterior Cervical Plating System

Indications for Use *(Describe)*

The NuVasive HELIX Anterior Cervical Plating System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive HELIX Anterior Cervical Plating System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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)

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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:

Ms. Priscila Saraiva
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
(858) 909-1807

Date Prepared: August 4, 2021

B. Device Name

Trade or Proprietary Name:	*NuVasive® Anterior Cervical Plate Systems*
Common or Usual Name:	Anterior Cervical Plate and Screw System
Regulation Name:	Spinal Intervertebral Body Fixation Orthosis
Regulatory Class:	Class II
Regulation Number:	21 CFR § 888.3060
Product Code:	KWQ

C. Predicate Devices

The subject *NuVasive Anterior Cervical Plate Systems* are substantially equivalent to the following devices:

Primary Predicate

- K071329 – NuVasive Helix ACP System

Additional Predicates

- K073275 – NuVasive Helix Mini ACP System
- K083341 – NuVasive Helix-T Anterior Cervical Plate System
- K093804 – NuVasive Helix Revolution ACP System
- K203253 – NuVasive ACP System
- K122910 – NuVasive Archon Anterior Cervical Plate System
- K131025 – NuVasive Archon Anterior Cervical Plate System
- K053581 – NuVasive SmartPlate Gradient Plus System

D. Device Description

The *NuVasive Anterior Cervical Plate Systems* are anterior cervical plating systems that consist of a variety of implant components including screws and plates, as well as associated manual general surgical instruments. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The subject devices components are from titanium (Ti-6Al-4V) conforming to ASTM F1472/F136 and ISO 5832-3, (titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 or ISO 5832-3, and nickel-cobalt-chromium-molybdenum alloy (MP35N) per ASTM F562.

Testing to assess the safety and compatibility of subject devices in the Magnetic Resonance (MR) Environment is in scope of this submission along with introducing sterile packaging to the Helix ACP System.

E. Indications for Use

The *NuVasive HELIX Anterior Cervical Plating System* is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive HELIX Anterior Cervical Plating System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

The *NuVasive ACP System* is intended for anterior screw fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The *NuVasive Archon Anterior Cervical Plate System* is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of the implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion. Additionally, the three-hole version of the implant system may be appropriate only for patients with large vertebral bodies and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.

WARNING: The NuVasive Archon Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical. thoracic or lumbar spine.

The *NuVasive Gradient Plus Plate System* is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive Gradient Plus System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

F. Technological Characteristics

As was established in this submission, the subject NuVasive Anterior Cervical Plate Systems are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were 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, function, and range of sizes.

G. Performance Data

Testing to assess the safety and compatibility of subject devices in the Magnetic Resonance (MR) Environment was presented. Below is the list Magnetic resonance imaging (MRI) compatibility testing that were conducted as per the FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014 and the standards:

1. Magnetically induced displacement force (ASTM F2052)
2. Magnetically induced torque (ASTM F2213)
3. Radiofrequency (RF) induced heating (ASTM F2182)
4. MR image artifact (ASTM F2119)

Additionally, sterile packaging validations for the Helix ACP System were executed for purpose of this submission.

The results of these studies show that the subject *NuVasive Anterior Cervical Plate Systems* meet or exceed the performance of the predicate devices and do not introduce any new risks; therefore, the systems are substantially equivalent to the predicate devices.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NuVasive Anterior Cervical Plate Systems* have been shown to be substantially equivalent to legally marketed predicate devices.