May 20, 2020

NuVasive, Incorporated
Ivanna Lopez
Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K201078
Trade/Device Name: NuVasive® ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 21, 2020
Received: April 22, 2020

Dear Ivanna Lopez:

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'Neill, M.B.E.
Acting 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)*

K201078

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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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. Ivanna Lopez
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
(858) 909-3302

Date Prepared: May 19, 2020

B. Device Name

Trade or Proprietary Name:	*NuVasive® ACP System*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Spinal intervertebral body fixation orthosis
Device Class:	Class II
Classification:	21 CFR § 888.3060
Product Code:	KWQ

C. Predicate Devices

The subject *NuVasive ACP System* is substantially equivalent to the following devices:

Primary Predicate

- K191500 – NuVasive® ACP System

Additional Predicates

- K073275 – NuVasive Helix Mini ACP System

D. Device Description

The *NuVasive ACP System* is an anterior cervical plating system that consists 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 device components are manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 or ISO 5832-3. The *NuVasive ACP System* was initially cleared in K191500. In K191500, static torsion results were included for the predicate *NuVasive ACP System*. The tested construct varied slightly in design from the cleared device. After clearance, confirmatory ASTM F1717 mechanical testing was completed on the cleared design, which revealed lower results in static torsion. The purpose of this submission is to present the lower static torsion test values of the subject *NuVasive ACP System*, which remain greater than *Helix Mini ACP System* (K073275), the cited predicate for static torsion, in K191500. Additionally, minor design changes and a labeling update to the system are presented. The design changes are minor updates to the system since clearance in K191500. Select changes have been implemented via the add to file process. Additional design updates are

also being presented, which will be implemented pending review of the subject submission.

E. Indications for Use

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.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive ACP 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 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

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

- Static torsion, static compression bending, and dynamic compression bending testing per ASTM F1717

In addition to the testing above, Finite Elemental Analysis and engineering rationales were used to establish that the minor design updates introduced did not create a new worst case.

The results of these studies show that the subject *NuVasive ACP System* meets or exceeds the performance of the predicate device and does not introduce any new risks; therefore, the system is substantially equivalent to the predicate device.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NuVasive ACP System* has been shown to be substantially equivalent to legally marketed predicate devices.