July 3, 2019

NuVasive, Incorporated
Thao Huynh
Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K191169
Trade/Device Name: NuVasive® Camber Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: April 30, 2019
Received: May 1, 2019

Dear Thao Huynh:

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,

Ronald P. Jean, Ph.D.
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)*

K191169

Device Name

NuVasive® Camber Laminoplasty System

Indications for Use *(Describe)*

The NuVasive® Camber Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Camber Laminoplasty System is used to hold the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion, or impinging the spinal cord.

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

Thao Huynh
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 320-5256

Date Prepared: July 2, 2019

B. Device Name

Trade Name:	*NuVasive® Camber Laminoplasty System*
Common Name:	Spinal Interlaminal Fixation Orthosis
Classification Name:	Orthosis, Spine, Plate, Laminoplasty, Metal
Regulation Number:	21 CFR § 888.3050
Product Code:	NQW

C. Predicate Devices

The subject *NuVasive® Camber Laminoplasty System* is substantially equivalent to the primary predicate device, *NuVasive® Laminoplasty Fixation System & LeVerage LFS System* (K1091623), and additional predicate *Medtronic Centerpiece Plate Fixation System* (K050082). *NuVasive® VuePoint® II OCT System* (K180198) and *NuVasive Affix II Spinous Process Plate System* (K132411) are also used as reference predicates.

D. Device Description

The *NuVasive® Camber Laminoplasty System* consists of plates and screws of various sizes made from titanium alloy (ASTM F136) to provide reinforcement while expanding the spinal canal and preserving the posterior elements. Instruments required to implant the device are also available.

E. Indications for Use

The *NuVasive® Camber Laminoplasty System* is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The *Camber Laminoplasty System* is used to hold the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion, or impinging the spinal cord.

F. Technological Characteristics

As was established in this submission, the subject *Camber Laminoplasty 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 devices through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

Non-clinical testing was performed to demonstrate that the subject *Camber Laminoplasty System* is substantially equivalent to other predicate devices. Engineering rationale and the following testing was performed:

- Axial Pullout (per ASTM F2193)
- Static 3-Point Bend
- Dynamic 3-Point Bend

The results demonstrate that the subject *Camber Laminoplasty System* meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate. No clinical studies were conducted.

H. Conclusions

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