August 24, 2018

NuVasive, Incorporated
Jessica Silverman
Regulatory Affairs Specialist
7475 Lusk Blvd.
San Diego, California 92121

Re: K181386
Trade/Device Name: NuVasive® Brigade® Lateral System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 31, 2018
Received: August 1, 2018

Dear Ms. Silverman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K181386

Device Name
NuVasive® Brigade® Lateral System

Indications for Use *(Describe)*

The Brigade® Lateral System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade® Lateral System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Brigade® Lateral System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade® Lateral System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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

Date Prepared: May 24, 2018

B. Device Name

Trade or Proprietary Name:	*NuVasive® Brigade® Lateral System*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Device Class:	Class II
Classification:	21 CFR § 888.3080
Product Code:	OVD

C. Predicate Devices

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

Primary Predicate

- K161230 – NuVasive Lumbar Interbody Implants

Additional Predicates

- K123045 – NuVasive Brigade Hyperlordotic System
- K100043 – CoRoent XLR Standalone System

D. Device Description

The *NuVasive® Brigade® Lateral System* is an interfixated interbody system manufactured from PEEK and titanium alloy conforming to industry recognized standards. The *NuVasive Brigade Lateral System* is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The *Brigade Lateral System* intervertebral fusion device is composed of a PEEK interbody implant containing radiographic titanium alloy markers, and two (2) titanium alloy bone screws. The subject device components are made from Polyetheretherketone (PEEK-OPTIMAL LT1) conforming to ASTM F2026 and titanium alloy (Ti-6A-4V ELI) conforming to ASTM F136 and ISO 5832-3 or (Ti-6A-4V) conforming to ASTM F1472. The purpose of this Premarket Notification in to implement design changes to the Brigade System previously cleared in K161230 (*NuVasive® Lumbar Interbody Implant*).

E. Indications for Use

The Brigade® Lateral System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade® Lateral System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Brigade® Lateral System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade® Lateral System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

F. Technological Characteristics

As was established in this submission, the subject *Brigade® Lateral 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

Finite Elemental Analysis (FEA) and engineering rationale were provided as evidence that the modified design of the *Brigade® Lateral System* construct did not create a new worst case for performance testing. The results of testing and Finite Elemental Analysis demonstrate that the subject *Brigade Lateral System* is substantially equivalent to predicate devices. No non-clinical or clinical studies were conducted.

H. Conclusions

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