June 16, 2023

NuVasive, Incorporated
Alexander R. Stevens
Regulatory Affairs Specialist
7475 Lusk Blvd
San Diego, California 92121

Re: K230894
Trade/Device Name: NuVasive Modulus ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: March 30, 2023
Received: March 31, 2023

Dear Alexander R. Stevens:

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,

Brent Showalter -S

Brent Showalter, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230894

Device Name

NuVasive Modulus ALIF System

Indications for Use *(Describe)*

The NuVasive Modulus ALIF System is indicated for spinal fusion procedures in skeletally mature patients. These devices are intended to be used with bone screws, anchoring blades, or a combination of the two. When used with Modulus ALIF bone screws, the Modulus ALIF System 10° - 20° lordotic cages may be used as a standalone system. When used with Modulus ALIF anchoring blades, the Modulus ALIF Interfixated System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared for use in the lumbar spine. When used with either the Modulus ALIF bone screws or the Modulus ALIF anchoring blades, the Modulus ALIF Interfixated system 25°- 30° lordotic cages must be used with supplemental internal spinal fixation systems that are cleared for use in the lumbar spine. The System is designed for use with autogenous bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Modulus ALIF 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), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and imaging studies (e.g., radiographs, CT scan, MRI scan). The Modulus ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolistheses and spinal stenosis at one or two adjacent levels, the Modulus ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by FDA for use in the lumbar spine in addition to the integrated screws/anchoring blades.

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.

510(k) Summary
In accordance with Title 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Alexander R. Stevens
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (347) 620-3110

Date Prepared: June 13, 2023

B. Device Name

Trade or Proprietary Name:	*NuVasive Modulus ALIF 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, MAX

C. Predicate Devices

The subject device of this premarket submission are substantially equivalent to the following predicate devices:

Primary

- *NuVasive Modulus ALIF System (*Previously known as 3DP Interfixated ALIF System*)* – K193593

Additional

- *NuVasive Modulus ALIF System* – K210271
- *NuVasive Thoracolumbar Interbody Systems* – K203714
- *Globus Medical Hedron IA Integrated Lumbar Spacers* – K191391

D. Device Description

The subject *NuVasive Modulus ALIF System* interbody implants are manufactured from titanium alloy (Ti-6Al-4V ELI) powder conforming to ASTM F3001 Class C. The solid and porous structures are simultaneously built using a powder bed fusion method. The hollow core, or graft aperture, allows for packing of graft to aid in the promotion of a solid fusion. Similarly, the macroporous internal lattice structure provides additional space for graft packing. The microporous, textured surface on the superior and inferior ends of the device serves to grip the adjacent vertebrae to resist migration of the device. The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. When used with the Modulus ALIF bone screws, the Modulus

ALIF Interfixated System 10°- 20° lordotic cages may be used as a standalone system. When used with the Modulus ALIF anchoring blades, the Modulus ALIF Interfixated System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared for use in the lumbar spine. When used with either the Modulus ALIF bone screws or the Modulus ALIF anchoring blades, the Modulus ALIF Interfixated system 25°- 30° lordotic cages must be used with supplemental internal spinal fixation systems that are cleared for use in the lumbar spine.

The purpose of this submission is to introduce the Modulus ALIF anchoring blades (blades), which are a new in-line fixation option, provided sterile and non-sterile, for the *NuVasive Modulus ALIF System*.

E. Intended Use

NuVasive Modulus ALIF System

The *NuVasive Modulus ALIF System* is indicated for spinal fusion procedures in skeletally mature patients. These devices are intended to be used with bone screws, anchoring blades, or a combination of the two. When used with Modulus ALIF bone screws, the Modulus ALIF System 10° - 20° lordotic cages may be used as a standalone system. When used with Modulus ALIF anchoring blades, the Modulus ALIF Interfixated System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared for use in the lumbar spine. When used with either the Modulus ALIF bone screws or the Modulus ALIF anchoring blades, the Modulus ALIF Interfixated system 25°- 30° lordotic cages must be used with supplemental internal spinal fixation systems that are cleared for use in the lumbar spine. The System is designed for use with autogenous bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Modulus ALIF 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), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and imaging studies (e.g., radiographs, CT scan, MRI scan). The Modulus ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolistheses and spinal stenosis at one or two adjacent levels, the Modulus ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by FDA for use in the lumbar spine in addition to the integrated screws/anchoring blades.

F. Technological Characteristics

As established in this eSTAR submission, the subject *NuVasive Modulus ALIF System* is substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have substantially equivalent technological characteristics to the predicate devices through comparison of design, intended use, material composition, function, and range of sizes.

G. Performance Data

The purpose of this submission is to introduce the Modulus ALIF anchoring blades. Mechanical performance testing was conducted to assess the safety and compatibility of the subject device. The following testing was performed:

- F2077 Static & Dynamic Axial Compression
- F2077 Static & Dynamic Compression-Shear
- Fixation Push-Out
- Gravimetric and Particulate Analysis
- Adjacent-Level Impingement Trajectory (Engineering Analysis)
- Subsidence
- Taber Abrasion
- Stereological Evaluation and Metallurgical Analysis

The results of these studies demonstrate that the subject *NuVasive Modulus ALIF System* is 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 Modulus ALIF System* has been shown to be substantially equivalent to the legally marketed predicate devices.