October 29, 2020

NuVasive, Incorporated
Jessica LeBlanc
Associate Manager, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K201692
Trade/Device Name: NuVasive Modulus XLIF Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM, OVD
Dated: October 1, 2020
Received: October 2, 2020

Dear Ms. LeBlanc:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201692

Device Name
NuVasive Modulus XLIF Interbody System

Indications for Use *(Describe)*
The NuVasive Modulus XLIF Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. When used with or without the Modulus XLIF internal fixation, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Modulus XLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use in the lumbar spine from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive Modulus XLIF Interbody System is also indicated for use in the treatment of multilevel degenerative scoliosis in the thoracolumbar 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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NUVASIVE

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:

Jessica LeBlanc
Associate Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3302

Date Prepared: October 1, 2020

B. Device Name

Trade or Proprietary Name:	*NuVasive® Modulus XLIF Interbody 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:	MAX, PHM, OVD

C. Predicate Devices

The subject *NuVasive Modulus XLIF Interbody System* is substantially equivalent to the primary predicate device *Modulus XLIF Interbody System* cleared in 510(k) K192760 and additional predicates *NuVasive Modulus XLIF Interbody System* (K163230) and *NuVasive CoRoent Ti-C System* (K140319).

D. Device Description

The subject *NuVasive Modulus XLIF Interbody System* are interbody implants manufactured from titanium alloy (Ti-6Al-4V ELI) powder conforming to ASTM F3001. 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. An optional internal fixation plate with bone screw(s) manufactured from titanium alloy (Ti-6Al-4V ELI) conforming ASTM F136 or ISO 5832-3 and MP35N conforming to ASTM F562 may be affixed to the adjacent vertebral body or bodies to provide additional migration resistance and stability. When used with or without the internal fixation plate and bone screws, the device is intended to be used with supplemental spinal fixation systems that are cleared by the FDA for use in the thoracolumbar spine.

The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. The device is intended to be used with supplemental spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

The purpose of this submission relates to a manufacturing change to the *Modulus XLIF* interbody implants.

E. Indications for Use

The NuVasive Modulus XLIF Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. When used with or without the Modulus XLIF internal fixation, the system is intended for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Modulus XLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use in the lumbar spine from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive Modulus XLIF Interbody System is also indicated for use in the treatment of multilevel degenerative scoliosis in the thoracolumbar spine.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Modulus XLIF Interbody 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, and function. This device does not contain software or electrical equipment.

G. Performance Data

Non-clinical testing and engineering analysis and rationale were performed to demonstrate that the subject *NuVasive Modulus XLIF Interbody System* is substantially equivalent to other predicate devices. The following testing and analysis were performed:

- Static and Dynamic Compression (per ASTM F2077)
- Static and Dynamic Compression-Shear (per ASTM F2077)
- Gravimetric and Particulate analysis (per ASTM F1714 and F1877)

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

H. Conclusions

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