June 21, 2022

NuVasive, Incorporated
Krunal Shah
Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K220478
Trade/Device Name: NuVasive MOD-EX XLIF Interbody System, NuVasive MOD-EX XLIF Plated 2.0 Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM, MQV
Dated: May 18, 2022
Received: May 19, 2022

Dear Krunal Shah:

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, 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.*

510(k) Number *(if known)*

K220478

Device Name

NuVasive MOD-EX XLIF Interbody System
NuVasive MOD-EX XLIF Plated 2.0 Interbody System

Indications for Use *(Describe)*

The NuVasive MOD-EX XLIF Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. When used with or without the MOD-EX XLIF internal fixation, the system is intended for use with autogenous and/or 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 and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. When ≥20° lordosis is needed, the plated MOD-EX XLIF Interbody must be used along with additional supplemental fixation. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive MOD-EX XLIF Plated 2.0 Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is intended for use with autogenous and/or 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 and supplemental internal 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 MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System are intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended 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 MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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:

Krunal Shah
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 458-2272
Date Prepared: May 18, 2022

### B. Device Name

| | |
|---|---|
| Trade or Proprietary Name: | *NuVasive MOD-EX XLIF Interbody System* |
| Common or Usual Name: | Intervertebral Body Fusion Device |
| Classification Name: | Intervertebral Body Fusion Device |
| Trade or Proprietary Name: | *NuVasive MOD-EX XLIF Plated 2.0 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, MQV |

### C. Predicate Devices

The subject *NuVasive MOD-EX XLIF Interbody System and NuVasive MOD-EX XLIF Plated 2.0 Interbody System* are substantially equivalent to multiple predicate devices. *NuVasive MOD-EX XLIF Interbody System* (K210439) serves as the primary predicate device, *while NuVasive Thoracolumbar Interbody system (K203714), NuVasive Modulus XLIF Interbody system* (K163230), *NuVasive Decade Lateral Plate System* (K130868), and the *NuVasive Lumbar Interbody Implants* (K161230) are additional predicate devices.

### D. Device Description

The *NuVasive MOD-EX XLIF Interbody System* and *NuVasive MOD-EX XLIF Plated 2.0 Interbody System* are an expandable interbody system, additively manufactured from Grade 23 titanium alloy (Ti-6Al-4V ELI) powder conforming to ASTM F3001 Class C and traditionally manufactured from titanium alloy (Ti-6V-4Al ELI) per ASTM F136 or ISO 5832-3. The *NuVasive MOD-EX XLIF Interbody System* also includes Nickel-Cobalt-Chromium-Molybdenum (MP35N) conforming to ASTM F562. The *NuVasive MOD-EX XLIF* and *NuVasive MOD-EX XLIF Plated 2.0* interbodies are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The system is designed to address thoracolumbar pathologies utilizing interbody placement through a standard lateral (XLIF) approach. The device features independent threaded drive and wedge mechanisms to allow for independent expansion of the anterior and posterior aspect of the implant. The superior and inferior endplate components are solid and porous structures

manufactured simultaneously using a powder bed fusion method. The microporous, textured surfaces on the superior and inferior ends of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. The *NuVasive MOD-EX XLIF and NuVasive MOD-EX XLIF Plated 2.0 Interbody System* interbodies have superior and inferior graft apertures, allowing for packaging of graft to aid in the promotion of a solid fusion.

**E. Indications for Use**

The NuVasive MOD-EX XLIF Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. When used with or without the MOD-EX XLIF internal fixation, the system is intended for use with autogenous and/or 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 and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. When ≥20° lordosis is needed, the plated MOD-EX XLIF interbody must be used along with additional supplemental fixation. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive MOD-EX XLIF Plated 2.0 Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is intended for use with autogenous and/or 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 and supplemental internal 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 MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System are intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended 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 MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

**F. Technological Characteristics**

As was established in this submission, the subject *MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System* are 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

The purpose of this submission is to introduce MR Conditional Labelling, expand the indications for use to include use of bone void filler for the *NuVasive MOD-EX XLIF Interbody System* and obtain premarket clearance for the *NuVasive MOD-EX XLIF Plated 2.0 Interbody System*.

Nonclinical testing was performed to demonstrate that the subject *MOD-EX XLIF Plated 2.0 Interbody System* is substantially equivalent to other predicate devices. The following testing was performed:

- Dynamic Axial Compression testing per ASTM F2077
- Dynamic torsion testing per ASTM F2077
- Gravimetric and Particulate analysis (ASTM F1714 and F1877)
- Screw push-out analysis
- Subsidence analysis

Testing to assess the safety and compatibility of subject devices in the Magnetic Resonance (MR) Environment was presented. Below is the list Magnetic resonance imaging (MRI) compatibility testing that were conducted as per the FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014, and the standards:

- Magnetically induced displacement force (ASTM F2052)
- Magnetically induced torque (ASTM F2213)
- Radiofrequency (RF) induced heating (ASTM F2182)
- MR image artifact (ASTM F2119)

A clinical and engineering rationale was provided to address technological differences between the intervertebral body fusion devices included in the submission to support use of a bone void filler with MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System.

The results of these testing demonstrate that the subject *MOD-EX XLIF Interbody System and MOD-EX XLIF Plated 2.0 Interbody System* present no new worst-case for performance testing, and the subject device was therefore found to be substantially equivalent to the predicate devices.

## H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *MOD-EX XLIF Interbody System* and *MOD-EX XLIF Plated 2.0 Interbody System* have been shown to be substantially equivalent to legally marketed predicate devices.