



May 4, 2018

NuVasive, Incorporated
Manthan Damani
Senior Regulatory Affairs Specialist
7475 Lusk Blvd.
San Diego, California 92121

Re: K173892

Trade/Device Name: NuVasive® XLX Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM, OVD
Dated: April 4, 2018
Received: April 5, 2018

Dear Manthan Damani:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173892

Device Name

NuVasive® XLX Interbody System

Indications for Use (Describe)

The NuVasive XLX 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 XLX internal fixation, the system is intended for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. XLX interbody devices expanded to $\geq 20^\circ$ lordosis must be used with the XLX internal fixation and additional supplemental fixation. The devices are to be used in patients who have had at least six months of non-operative treatment.

The XLX Interbody System is 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 XLX Interbody System can 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.

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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:

Manthan J. Damani
Senior Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 458-2272

Date Prepared: April 4, 2018

B. Device Name

Trade or Proprietary Name:	<i>NuVasive® XLX Interbody System</i>
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 *XLX Interbody System* is substantially equivalent to multiple predicate devices. *NuVasive Modulus XLIF Interbody System* (K172123) serves as the primary predicate device, while *NuVasive TLX Interbody System* (K171633), *NuVasive MLX – Medial Lateral Expandable Lumbar Interbody System* (K140770), *NuVasive Lumbar Interbody Implants* (K161230) and *Vertera Coalesce Lumbar Interbody Fusion System* (K163506) are additional predicate devices.

D. Device Description

The *NuVasive XLX Interbody System* is an expandable interbody system manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F136 and ISO 5832-3, and nickel-cobalt-chromium-molybdenum (MP35N) conforming to ASTM F562. XLX interbodies are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The *XLX Interbody* intervertebral fusion device is designed to address thoracolumbar pathologies utilizing interbody placement through a standard lateral (XLIF) approach. The hollow core, or graft aperture, allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to aid in the promotion of a solid fusion. An internal fixation plate with bone screw 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 to provide additional migration resistance and stability. When used with or without the internal fixation plate and bone screw, the device is intended to be used with supplemental spinal fixation systems that are cleared by the FDA for use in the thoracolumbar spine.

**E. Indications for Use**

The NuVasive® XLX 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 XLX internal fixation, the system is intended for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. XLX interbody devices expanded to $\geq 20^\circ$ lordosis must be used with the XLX internal fixation and additional supplemental fixation. The devices are to be used in patients who have had at least six months of non-operative treatment.

The XLX Interbody System is 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 XLX Interbody System can 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 *XLX 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.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *XLX Interbody System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic axial compression testing per ASTM F2077
- Static and dynamic compression-shear testing per ASTM F2077
- Dynamic torsion testing per ASTM F2077
- Static push-out testing per ASTM draft standard F-04.25.02.02 (work item Z8423Z)
- Screw push-out analysis
- Subsidence analysis

The results demonstrate that the subject *XLX Interbody System* presents 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 *XLX Interbody System* has been shown to be substantially equivalent to legally marketed predicate devices.
