



NuVasive, Incorporated  
Cynthia Adams  
Sr. Specialist, Regulatory Affairs  
7475 Lusk Blvd.  
San Diego, California 92121

February 8, 2018

Re: K173025

Trade/Device Name: NuVasive® MLX® - Medial Lateral Expandable Lumbar Interbody System,  
NuVasive® AP Expandable XLIF System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Regulatory Class: Class II

Product Code: MAX, PHM

Dated: January 8, 2018

Received: January 9, 2018

Dear Ms. Adams:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2020  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)  
K173025

Device Name  
NuVasive® MLX® - Medial Lateral Expandable Lumbar Interbody System

### Indications for Use (Describe)

The NuVasive MLX- Medial Lateral Expandable Lumbar 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 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 NuVasive MLX- Medial Lateral Expandable Lumbar 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 MLX- Medial Lateral Expandable Lumbar 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2020  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)  
K173025

Device Name  
NuVasive® AP Expandable XLIF System

### Indications for Use (Describe)

The NuVasive AP Expandable XLIF 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 and supplemental internal spinal fixation systems (e.g., pedicle screw/rod 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 AP Expandable XLIF 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 AP Expandable XLIF 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 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:

Cynthia Adams  
Senior Specialist, Regulatory Affairs  
NuVasive, Incorporated  
7475 Lusk Blvd.  
San Diego, California 92121  
Telephone: (858) 909-1800

Date Prepared: January 8, 2018

### B. Device Name

Trade or Proprietary Name: *NuVasive® MLX® – Medial Lateral Expandable Lumbar Interbody System*  
*NuVasive® AP Expandable XLIF 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

### C. Predicate Devices

The subject *NuVasive MLX and APX Interbody Devices* are substantially equivalent to the primary predicate device, *CoRoent Thoracolumbar System* (K170962) and additional predicate devices, *NuVasive® MLX™ – Medial Lateral Expandable Lumbar Interbody System* (K153105) and *AP Expandable XLIF System* (K140162).

### D. Device Description

The *NuVasive MLX and APX Interbody Devices* are manufactured from Ti-6Al-4V ELI conforming to ASTM F136 and ISO 5832-3, Ti-6Al-4V conforming to ASTM 1472, and Nitinol SE508 conforming to ASTM F2063. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. This scope of this 510(k) includes expanded indications for use and minor add-to-file changes.

---

**E. Indications for Use**

The NuVasive MLX- Medial Lateral Expandable Lumbar 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 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 NuVasive MLX- Medial Lateral Expandable Lumbar 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 MLX- Medial Lateral Expandable Lumbar Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

The NuVasive AP Expandable XLIF 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 and supplemental internal spinal fixation systems (e.g., pedicle screw/rod 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 AP Expandable XLIF 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 AP Expandable XLIF 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 *NuVasive MLX and APX Interbody Devices* are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were 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 sterilization method.

**G. Performance Data**

Mechanical performance testing data was provided as part of the previous submissions to establish substantial equivalence for their use. The previously presented mechanical testing data are sufficient to support the subject system and does not warrant the need for additional nonclinical testing. Therefore, no new mechanical testing was performed for this 510(k) submission.

---

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST72:2011/(R)2016.

**H. Conclusions**

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *NuVasive MLX and APX Interbody Devices* have been shown to be substantially equivalent to legally marketed predicate devices.

---