DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 6, 2015

NuVasive, Incorporated
Ms. Olga Lewis
Lead Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K151374
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
Dated: May 21, 2015
Received: May 22, 2015

Dear Ms. Lewis:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151374

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 bone graft to facilitate fusion. The AP Expandable XLIF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the AP Expandable XLIF System. The AP Expandable XLIF System is intended to be used with supplemental internal spinal fixation systems (e.g., pedicle screw/ rod systems) that are cleared by the FDA for use in the lumbar 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151374

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 bone graft to facilitate fusion. The MLX – Medial Lateral Expandable Lumbar Interbody System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the MLX – Medial Lateral Expandable Lumbar Interbody System. The MLX – Medial Lateral Expandable Lumbar Interbody System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

Olga Lewis
Lead Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: July 17, 2015

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

C. Predicate Devices

The subject *Sterile MLX and APX Interbody Devices* are substantially equivalent to the primary predicate device, *Renovis S141 Lumbar Interbody Cage System* (K143126) and additional predicate devices, *NuVasive® MLX™ – Medial Lateral Expandable Lumbar Interbody System* (K140770) and *AP Expandable XLIF System* (K140162).

D. Device Description

The *NuVasive Sterile 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, Nitinol SE508 conforming to ASTM F2063, and Nickel-Cobalt-Chromium-Molybdenum alloy (MP35N) conforming to ASTM F562. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. This 510(k) covers addition of sterile packaged implants to previously cleared systems.

E. Indications for Use

The *NuVasiveMLX – 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 bone graft to facilitate fusion. The *MLX – Medial Lateral Expandable Lumbar Interbody System* is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the *MLX – Medial Lateral Expandable Lumbar Interbody System*. The *MLX – Medial Lateral Expandable Lumbar Interbody System* is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

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 bone graft to facilitate fusion. The *AP Expandable XLIF System* is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the AP Expandable XLIF System. The AP Expandable XLIF System is intended to be used with supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) that are cleared by the FDA for use in the lumbar spine.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Sterile 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

Gamma sterilization validation, sterile packaging performance validation and the integrity of the sterile barrier over time validation was performed to qualify new packaging and sterilization method for the *Sterile MLX and APX Interbody Devices*.

The results demonstrate that the subject *Sterile MLX and APX Interbody Devices* are substantially equivalent to the predicate devices.

H. Conclusions

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