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

Re: K171633
Trade/Device Name: NuVasive® TLX Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: September 1, 2017
Received: September 5, 2017

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.

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the
Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or
(301) 796-7100 or at its Internet address

Sincerely,

Mark N. Melkerson -S

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

Enclosure
NuVasive® TLX Interbody System

Indications for Use (Describe)

The NuVasive TLX 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 TLX 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 TLX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

*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:

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"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: September 1, 2017

B. Device Name
   Trade or Proprietary Name: NuVasive® TLX 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

C. Predicate Devices
   The subject TLX Interbody System is substantially equivalent to multiple predicate devices. NuVasive CoRoent Thoracolumbar System (K170962) serves as the primary predicate device, while NuVasive TLX Interbody System (K153627), NuVasive CoRoent® System (K141665), NuVasive CoRoent System (K071795), NuVasive Lumbar Interbody Implants (K161230), and NuVasive MLX – Medial Lateral Expandable Lumbar Interbody System (K140770) are additional predicate devices.

D. Device Description
   The TLX Interbody intervertebral fusion device is designed to address lumbar pathologies utilizing interbody placement through a standard posterolateral approach. The NuVasive TLX Interbody System is manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3, and nickel-cobalt-chromium-molybdenum (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.
E. **Indications for Use**

The NuVasive TLX 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.

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F. **Technological Characteristics**

As was established in this submission, the subject TLX 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 TLX Interbody System is substantially equivalent to other predicate devices. The following testing was performed:

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

The results demonstrate that the subject TLX Interbody System presents no new worst-case for performance testing, and the subject device was therefore found to be substantially equivalent to the predicate.

H. **Conclusions**

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