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

February 20, 2015

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

Re: K142205
Trade/Device Name: NuVasive X-CORE® Expandable VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: January 22, 2015
Received: January 23, 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,

Lori A. Wiggins -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

Indications for Use

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

510(k) Number *(if known)*
K142205

Device Name
NuVasive X-CORE® Expandable VBR System

Indications for Use *(Describe)*
The NuVasive X-CORE® Expandable VBR System is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive X-CORE Expandable VBR System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

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:

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

Date Prepared: January 22, 2015

B. Device Name

Trade or Proprietary Name:	*NuVasive X-Core® Expandable VBR System*
Common or Usual Name:	Spinal Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis

Device Class:	Class II
Classification:	21 CFR § 888.3060
Product Code:	MQP

C. Predicate Devices

The subject *X-Core® Expandable VBR System* is substantially equivalent to the primary predicate device *NuVasive Expandable Lumbar Interbody System* (K090176) and additional predicate devices *NuVasive Mesh* (K032476), *Osteotech VBR* (K012254), *DePuy Surgical Titanium Mesh System* (K030349), and *Synthes Spine Synex Spacer System* (K003836 and K061891).

D. Device Description

The *X-Core® Expandable VBR System* is manufactured from Ti-6Al-4V ELI conforming to ASTM F136 and ISO 5832-3. 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 design changes to *NuVasive Expandable Lumbar Interbody System* (K090176).

E. Intended Use

The *NuVasive X-CORE® Expandable VBR System* is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The *NuVasive X-CORE Expandable VBR System* is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive X-CORE Expandable VBR 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, performance, material composition, and function.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NuVasive X-CORE Expandable VBR System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic Torsion per ASTM F2077
- Expulsion testing

The results demonstrate that the subject *NuVasive X-CORE Expandable VBR System* is substantially equivalent to predicate devices. No non-clinical or clinical studies were conducted.

H. Conclusions

Based on the indications for use, technological characteristics, mechanical testing, and comparison to predicate devices, the subject *NuVasive X-CORE Expandable VBR System* has been shown to be substantially equivalent to legally marketed predicate devices.