February 26, 2020

NuVasive Incorporated
Aditya Sharma
Sr. Regulatory Affairs Specialist
7475 Lusk Boulevard
San Diego, California 92121

Re: K193506
Trade/Device Name: NuVasive X-Core® Expandable VBR System, NuVasive X-Core® Mini Cervical Expandable VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: January 31, 2020
Received: February 3, 2020

Dear Aditya Sharma:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193506

Device Name
NuVasive X-CORE® Expandable VBR System and NuVasive X-CORE® Mini Cervical 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.

The NuVasive X-CORE® Mini Cervical Expandable VBR System is a vertebral body replacement device indicated for use in the cervical spine (C3-C7 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following Corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The NuVasive X-CORE® Mini Cervical Expandable VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.

These implants are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The NuVasive X-CORE® Mini Cervical Expandable VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft 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.

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

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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:

Aditya Sharma
Sr. Regulatory Affairs Specialist
NuVasive Incorporated
7475 Lusk Boulevard
San Diego, California 92121
Telephone: 858-480-0263

Date Prepared: December 17, 2019

B. Device name

Proprietary Name:	NuVasive X-Core® Expandable VBR System and NuVasive X-Core® Mini Cervical Expandable VBR System
Common or Usual Name:	Spinal Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Regulation Number:	21 CFR § 888.3060
Classification:	Class II
Product Code:	MQP, PLR

C. Predicate Devices

The subject device is substantially equivalent to the primary predicate device, X-Core Expandable VBR System (K142205) and additional predicate devices, X-Core Mini Cervical Expandable VBR System (K151651) and Modulus XLIF Interbody System (K192760).

D. Device Description

X-Core Expandable VBR and *X-Core Mini Cervical Expandable VBR* devices are vertebral body replacement devices manufactured from Titanium alloy Ti6Al-4V ELI conforming to ASTM F136 and ISO 5832-3. Devices are offered in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

The purpose of this 510(k) application is to add the sterile implants option to the previously cleared system.

E. Indications for 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

The *NuVasive X-Core Mini Cervical Expandable VBR System* is a vertebral body replacement device indicated for use in the cervical spine (C3-C7 vertebral bodies) in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following Corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The NuVasive X-Core Mini Cervical Expandable VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine.
These implants are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The NuVasive X-Core Mini Cervical Expandable VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

F. Technological Characteristics

As was established in this submission, the subject device is substantially equivalent to the predicate device cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and functions.

G. Performance Data

Gamma sterilization validation, sterile packaging validation, integrity of the sterile barrier over time validation are performed to qualify packaging and sterilization method for the subject device. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST72:2011.

H. Conclusions

The subject *X-Core Expandable VBR* and *X-Core Mini Expandable VBR System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.