November 20, 2018

NuVasive, Incorporated
Olga Lewis
Senior Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K180550
Trade/Device Name: NuVasive® Monolith™ Cervical Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: October 18, 2018
Received: October 19, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180550

Device Name
NuVasive® Monolith™ Cervical Corpectomy System

Indications for Use *(Describe)*
The NuVasive Monolith Cervical Corpectomy 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® Monolith Cervical Corpectomy 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® Monolith Cervical Corpectomy 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:

Olga Lewis
Senior Manger, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3360

Date Prepared: October 18, 2018

B. Device Name

Trade or Proprietary Name:	NuVasive® Monolith™ Cervical Corpectomy 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:	PLR

C. Predicate Devices

The subject *Monolith Cervical Corpectomy System* is substantially equivalent to a primary predicate device, *NuVasive X-Core® Mini Cervical Expandable VBR System* (K151651), and additional predicate devices, *Monolith Corpectomy System* (K170271) and *NuVasive CoRoent System* (K081611).

D. Device Description

The *NuVasive Monolith Cervical Corpectomy System* is a vertebral body replacement system manufactured from Polyetheretherketone (PEEK) Optima LT-1 conforming to ASTM F2026. The *Monolith Cervical Corpectomy System* is made up of two primary components: a core and a set of endcaps. The core is offered in a variety of shapes and sizes to suit individual pathology and anatomical conditions of the patient. The modular standard and railed endcaps are offered in multiple footprints and lordosis options.

The device contains pins made of either titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3 or tantalum conforming to ASTM F560 or ISO 13782 to serve as radiopaque markers. The system is provided non-sterile, and is designed to be sterilized by the user before each use.

The purpose of this 510(k) is to expand the indications for use of *NuVasive Monolith Corpectomy System* (K170271) to include the treatment of tumors, trauma, and degenerative disorders of the cervical spine.

E. Indications For Use

The *NuVasive Monolith Cervical Corpectomy 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 Monolith Cervical Corpectomy 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 Monolith Cervical Corpectomy 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

The subject *Monolith Cervical Corpectomy 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 have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.

G. Performance Data

Mechanical performance testing data was provided as part of previous submissions to establish substantial equivalence for its use as a vertebral body replacement in the throacolumbar spine: worst case devices included with the subject system were tested and cleared in these predicate 510(k) submissions. Additional dynamic compression and dynamic torsion testing per ASTM F2077 was performed for the subject device. The proposed expansion of the indications for use to include their use in the treatment of tumors, trauma, degenerative disorders, and osteomyelitis of the cervical spine does not create a new mechanical worst-case for any of the implants. Since no new device designs and no new worst case sizes are being introduced to the subject *NuVasive Monolith Cervical Corpectomy System*, the previously presented mechanical testing data along with additional dynamic testing data are sufficient to support the proposed expanded indications for use.

A retrospective clinical study was performed on patients with cervical degenerative disorders, tumor, fracture, and osteomyelitis treated with the subject device. Based on the clinical data, it was determined that the *NuVasive Monolith Cervical Corpectomy System* used in the treatment of cervical degenerative disorders, tumor, fracture, and osteomyelitis has a safety and effectiveness profile similar to the predicate device. Additionally, a clinical literature analysis of cervical corpectomy procedures was performed to support the use of the subject device.

The subject *NuVasive Monolith Cervical Corpectomy System* meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate.

No changes to the subject device have been made since the clearance in K170271. Comparison to the predicate devices was provided to support substantial equivalence.

H. Conclusions

Based on the indications for use, technological characteristics, mechanical testing, and comparison to predicate devices, the subject *Monolith Cervical Corpectomy System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.