DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 30, 2017

NuVasive, Incorporated
Cynthia Adams
Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K170271
Trade/Device Name: NuVasive® Monolith Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: January 26, 2017
Received: January 27, 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 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 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,

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)*

K170271

Device Name
NuVasive® Monolith Corpectomy System

Indications for Use *(Describe)*

The NuVasive® Monolith Corpectomy System is a partial or total 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 Monolith Corpectomy 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.

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:

Cynthia Adams
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: 858-320-4549

Date Prepared: January 26, 2017

B. Device Name

Trade or Proprietary Name:	NuVasive® Monolith 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:	MQP

C. Predicate Devices

The subject *Monolith Corpectomy System* is substantially equivalent to primary predicate device, *NuVasive PEEK Corpectomy System* (K151167), and additional predicate devices: *NuVasive PEEK Corpectomy Railed System* (K151538), *NuVasive X-CORE Expandable VBR System* (K142205), and reference device *NuVasive Lumbar Interbody Implants* (K161230).

D. Device Description

The *Monolith Corpectomy System* is a vertebral body replacement system manufactured from Polyetheretherketone (PEEK) Optima LT-1 conforming to ASTM F2026. The *Monolith 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 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 *Monolith Corpectomy System* is provided non-sterile to be sterilized by the user before each use.

E. Indications For Use

The *NuVasive® Monolith Corpectomy System* is a partial or total 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

Monolith Corpectomy 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

The subject *Monolith 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

Nonclinical testing was performed to demonstrate that the subject *Monolith Corpectomy System* is substantially equivalent to other predicate devices. The following testing and analysis was performed:

- Static Axial compression and torsion per ASTM F2077
- Push-out Analysis
- Subsidence Analysis
- MR Compatibility Analysis

Finite Elemental Analysis (FEA) and engineering rationale were also provided as evidence that the modified design of the *Monolith Corpectomy System* construct did not create a new worst case for performance testing. The results of the testing and Finite Elemental Analysis demonstrate that the subject *Monolith Corpectomy 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 *Monolith Corpectomy System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.