December 6, 2017

NuVasive, Incorporated
Ms. Michelle Cheung
Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K173153
Trade/Device Name: Vertera Spine™ Coalesce™ Thoracolumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: September 28, 2017
Received: September 29, 2017

Dear Ms. Cheung:

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.

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.

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,

Ronald P. Jean -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)*

K173153

Device Name
Vertera Spine™ Coalesce™ Thoracolumbar Interbody Fusion System

Indications for Use *(Describe)*

The Vertera Spine™ Coalesce™ Thoracolumbar Interbody Fusion 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 Vertera Spine Coalesce Thoracolumbar Interbody Fusion 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 Vertera Spine Coalesce Thoracolumbar Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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

Michelle Cheung
Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3360

Date Prepared: September 28, 2017

B. Device Name

Trade Name:	*Vertera Spine™ Coalesce™ Thoracolumbar Interbody Fusion 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 *Vertera Spine™ Coalesce™ Thoracolumbar Interbody Fusion System* is substantially equivalent to the primary predicate device, *Coalesce™ (-Straight, -Convex, -Crescent, -Lateral, -Anterior, or -Oblique) Lumbar Interbody Fusion System* (K163506), and additional predicate *NuVasive CoRoent Thoracolumbar System* (K170962).

D. Device Description

The *Vertera Spine Coalesce Thoracolumbar Interbody Fusion System* comprises of sterile, single use implant grade polyetheretherketone (PEEK) devices, available in varied footprints and heights, designed for supplemental stabilization of the thoracolumbar spinal column in thoracolumbar intervertebral body fusion procedures.

Each device within the *Coalesce System* is comprised of a continuous body of PEEK formed into the final product shape with a porous architecture on select faces of the implant. The porous architecture is derived directly from the implant body and is not a sintered or otherwise additive coating. In addition to PEEK, the device assembly may contain two or more tantalum markers, depending on footprint, to enable visibility under x-ray in vivo.

The purpose of this 510(k) submission is to expand indications for use to match indications for use of the predicate device, *NuVasive CoRoent Thoracolumbar System* (K170962).

E. Indications for Use

The *Vertera Spine™ Coalesce™ Thoracolumbar Interbody Fusion 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 *Vertera Spine Coalesce Thoracolumbar Interbody Fusion 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 *Vertera Spine Coalesce Thoracolumbar Interbody Fusion System* can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

F. Technological Characteristics

As was established in this submission, the subject *Vertera Spine Coalesce Thoracolumbar Interbody Fusion 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. This device does not contain software or electrical equipment.

G. Performance Data

Mechanical performance testing data was provided as part of the previous submissions to establish substantial equivalence for their use. Since no design changes are a part of the present submission, additional non clinical testing is not warranted. Therefore, no new mechanical testing was performed for this 510(k) submission.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *Vertera Spine Coalesce Thoracolumbar Interbody Fusion System* has been shown to be substantially equivalent to legally marketed predicate devices.