November 21, 2017

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

Re: K173030
Trade/Device Name: Vertera Spine™ Cohere® Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: September 27, 2017
Received: September 28, 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.

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 (DICE) 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 (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173030

Device Name
Vertera Spine™ Cohere® Cervical Interbody Fusion Device

Indications for Use *(Describe)*
The Vertera Spine™ Cohere® Cervical Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Vertera Spine Cohere Cervical Interbody Fusion Device is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion

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

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

Date Prepared: September 27, 2017

B. Device Name

Trade or Proprietary Name:	*Vertera Spine™ Cohere® Cervical Interbody Fusion Device*
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, cervical
Device Class:	Class II
Classification:	21 CFR § 888.3080
Product Code:	ODP

C. Predicate Devices

The subject *Vertera Spine™ Cohere® Cervical Interbody Fusion Device* is substantially equivalent to the primary predicate device, *Vertera Hedgehog Cervical Interbody Fusion Device* (K143685), and additional predicate *NuVasive CoRoent Small Interbody System* (K163491).

D. Device Description

The subject *Vertera Spine Cohere Cervical Interbody Fusion Device*, previously cleared as predicate *Vertera Hedgehog Cervical Interbody Fusion Device* (K143685), is an interbody fusion device comprised of a single, continuous piece of PEEK Scoria®, which is formed into a final product shape. The subject device remains solid with an extruded porous layer on the superior and inferior surfaces of the implant body. The porous surface is derived directly from the implant body and is not a sintered or otherwise additive coating. The hollow core or graft aperture allows for packing of autograft or allograft to help promote a solid fusion. The PEEK cage contains two marker bands made of tantalum conforming to ASTM F560 R05200, which serve as radiopaque markers so the location and orientation of the device may be seen radiographically, during and after the procedure for position confirmation. The *Vertera Spine Cohere Cervical Interbody Fusion Device* comes in a variety of sizes and geometries to suit the individual pathology and anatomical conditions of

the patient. The devices are provided sterile, with the accessory surgical instruments packaged as non-sterile to be sterilized by the end user. The *Vertera Spine Cohere Cervical Interbody Fusion Device* is intended to be used with supplemental fixation.

The purpose of this 510(k) submission is to expand indications for use to include use with allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. It also seeks to expand the indications for use to include the treatment of multilevel cervical disc degeneration and/or cervical spinal instability at multiple levels.

E. Indications for Use

The *Vertera Spine™ Cohere® Cervical Interbody Fusion Device* is indicated for intervertebral body fusion of the spine in skeletally mature patients. The *Vertera Spine Cohere Cervical Interbody Fusion Device* is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion

F. Technological Characteristics

As was established in this submission, the subject *Vertera Spine Cohere Cervical Interbody Fusion Device* 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 Cohere Cervical Interbody Fusion Device* has been shown to be substantially equivalent to legally marketed predicate devices.