DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2017

NuVasive, Incorporated
Martin Yahiro
Director, Medical Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K163491
Trade/Device Name: NuVasive® CoRoent® Small Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: February 24, 2017
Received: February 27, 2017

Dear Dr. Yahiro:

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)*
K163491

Device Name
NuVasive® CoRoent® Small Interbody System

Indications for Use *(Describe)*

The NuVasive CoRoent Small Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The NuVasive CoRoent Small Interbody System 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:

Martin Yahiro, M.D.
Medical Affairs Director
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: 858-638-5589

Date Prepared: March 22, 2017

B. Device Name

Trade or Proprietary Name:	NuVasive® CoRoent® Small Interbody System
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 *CoRoent Small Interbody System* is substantially equivalent to the primary predicate device, *NuVasive CoRoent Small Interbody System* (K150362).

D. Device Description

The *NuVasive CoRoent Small Interbody System* is a hollow interbody cage manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026. The implant contains a hollow core or graft aperture which allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft material to help promote a solid fusion. Rows of teeth on the surface of each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. The device includes marker pins composed of titanium alloy conforming to ASTM F136 and ISO 5832-3 or tantalum conforming to ASTM F560 or ISO 13782. The pins serve as radiopaque markers allowing the location and orientation of the device to be seen radiographically during and after the procedure for position confirmation.

The implants are available in flat or contoured endplates, and come 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) is to expand the indications for use to include the treatment of multilevel cervical disc degeneration and/or cervical spinal instability at up to four contiguous levels.

E. Indications for Use

The NuVasive CoRoent Small Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The NuVasive CoRoent Small Interbody System 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

The subject *CoRoent Small Interbody 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

The purpose of this 510(k) is to modify the Indications for Use for the subject *CoRoent Small Interbody System*. A retrospective clinical study of patients with cervical spondylosis including the following additional pathologies (with or without radiculopathy and/or myelopathy) - cervical disc degeneration, herniated nucleus pulposus (HNP), stenosis, deformity, and/or instability - were treated with the subject device. Based on the clinical data, it was determined that the *CoRoent Small Interbody System* used in the treatment of 3- and 4-level cervical disc degeneration has a safety and effectiveness profile similar to the predicate device. Additionally, a clinical literature analysis of multilevel anterior cervical discectomy and fusion (ACDF) was performed to support the use of the subject device at 3 and 4 cervical levels. No other changes have been made to the interbodies since their clearance in the *CoRoent Small Interbody System* 510(k) K150362. Therefore, no new nonclinical testing was performed for the purpose of this submission.

H. Conclusions

Based on the technological characteristics, clinical literature analysis, retrospective clinical study and comparison to predicate devices, the subject *CoRoent Small Interbody System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.