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

September 28, 2016

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

Re: K161442
Trade/Device Name: NuVasive® CoRoent® Small Interlock™ System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: September 8, 2016
Received: September 9, 2016

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 Parts 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" (21CFR 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)*
K161442

Device Name
NuVasive® CoRoent® Small Interlock™ System

Indications for Use *(Describe)*
The NuVasive CoRoent Small Interlock System is an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one level from C2-T1. The NuVasive CoRoent Small Interlock System (lordotic angles of 10° and 15°) is a standalone system. The NuVasive CoRoent Small Interlock System (lordotic angles of 20° to 30°) must be used with supplemental fixation cleared by the FDA. The System is intended to be used with autogenous or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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:

Cynthia Adams
Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: September 14, 2016

B. Device Name

Trade or Proprietary Name:	*NuVasive® CoRoent® Small Interlock™ 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:	OVE

C. Predicate Devices

The subject *NuVasive CoRoent Small Interlock System* is substantially equivalent to multiple predicate devices. *NuVasive CoRoent Small Interlock System* (K142299) serves as the primary predicate device, while *NuVasive CoRoent Interlock System* (K102547) is an additional predicate device. *NuVasive CoRoent Small Interbody System* (K140921), *NuVasive CoRoent System* (K081611) and *NuVasive Archon Anterior Cervical System* (K131025) are additional predicate devices.

D. Device Description

The *NuVasive CoRoent Small Interlock System* is a standalone anterior cervical interbody device consisting of a PEEK (polyetheretherkeytone) implant cage with titanium alloy and tantalum radiographic markers, titanium alloy washers, and three (3) titanium alloy bone fixation screws. The devices are manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026, titanium alloy conforming to ASTM F136 and tantalum conforming to ASTM F560 or ISO 13782. The implants are available in a variety of sizes to accommodate anatomical conditions. The *NuVasive CoRoent Small Interlock System* is a standalone system intended to be used with the bone screws provided, and when used as such requires no additional supplementary fixation systems.

E. Indications for Use

The NuVasive CoRoent Small Interlock System is an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one level from C2-T1. The NuVasive CoRoent Small Interlock System (lordotic angles of 10° and 15°) is a standalone system. The NuVasive CoRoent Small Interlock System (lordotic angles of 20° to 30°) must be used with supplemental fixation cleared by the FDA. The System is intended to be used with autogenous or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive CoRoent Small Interlock 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

Nonclinical testing was performed to demonstrate that the subject *NuVasive CoRoent Small Interlock System* is substantially equivalent to other predicate devices. The following testing and analysis was performed:

- Static and dynamic compression testing per ASTM F2077
- Static and dynamic torsion testing per ASTM F2077
- Wear debris/mass change analysis during ASTM F2077, per ASTM F1877 and ASTM F1714
- Static push-out testing per ASTM Work Item Z8423Z
- Subsidence analysis per ASTM F2267

The results of these studies show that the subject *NuVasive CoRoent Small Interlock System* meets or exceeds the performance of the predicate device and does not introduce any new risks; therefore, the system is substantially equivalent to the predicate devices.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *NuVasive CoRoent Small Interlock System* has been shown to be substantially equivalent to legally marketed predicate devices.