



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

NuVasive, Incorporated
Cynthia Adams
Senior Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

June 8, 2017

Re: K170961
Trade/Device Name: NuVasive CoRoent Small Interlock II System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: March 30, 2017
Received: March 31, 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

Indications for Use

K170961

Device Name

NuVasive CoRoent Small Interlock II System

Indications for Use (Describe)

The NuVasive CoRoent Small Interlock II 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 CoRoent Small Interlock II System (lordotic angles of 7° to 15°) is a standalone system. The CoRoent Small Interlock II 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.

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

Date Prepared: March 30, 2017

B. Device Name

Trade or Proprietary Name:	<i>NuVasive CoRoent Small Interlock II System</i>
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Integrated Fixation, Cervical

Device Class:	Class II
Classification:	21 CFR § 888.3080
Product Code:	OVE

C. Predicate Devices

The subject *CoRoent Small Interlock II System* is substantially equivalent to multiple predicate devices. *NuVasive CoRoent Small Interlock System* (K161442) serves as the primary predicate device, while *NuVasive CoRoent Interlock System* (K102547), *NuVasive CoRoent Interlock System* (K142299), *NuVasive CoRoent Ti-C System* (K163707), *NuVasive CoRoent Small Ti-C System* (K162138), and *NuVasive CoRoent System* (K081611) are additional predicate devices.

D. Device Description

The *NuVasive CoRoent Small Interlock II System* is an anterior cervical interbody device consisting of a PEEK-OPTIMA[®] (poly-ether-ether-ketone) implant cage with commercially pure titanium coating, 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, commercially pure titanium conforming to ASTM F1580, 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.

E. Indications for Use

The *NuVasive CoRoent Small Interlock II 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 *CoRoent Small Interlock II System* (lordotic angles of 7° to 15°) is a standalone system. The *CoRoent Small Interlock II 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 *CoRoent Small Interlock II 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 *CoRoent Small Interlock II 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
- Subsidence and push-out analysis
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

The results of these studies show that the subject *CoRoent Small Interlock II 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 *CoRoent Small Interlock II System* has been shown to be substantially equivalent to legally marketed predicate devices.
