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

October 26, 2016

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

Re: K162138
Trade/Device Name: NuVasive® CoRoent® Small Ti-C System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 29, 2016
Received: August 1, 2016

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 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)*

K162138

K162138

Device Name
NuVasive® CoRoent® Small Ti-C System

Indications for Use *(Describe)*

The NuVasive CoRoent Small Ti-C System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Ti-C System is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation; the CoRoent Small interbody devices with lordotic angles of 10° or greater are required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/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)

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)*

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: October 24, 2016

B. Device Name

Trade or Proprietary Name:	*NuVasive® CoRoent® Small Ti-C 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 *NuVasive CoRoent Small Ti-C System* is substantially equivalent to primary predicate device *NuVasive CoRoent Small Interbody System* (K150362), and additional predicates *CoRoent Ti-C System* (K160916), *NuVasive CoRoent Ti-C System* (K140319) and *NuVasive CoRoent System* (K081611).

D. Device Description

The *NuVasive CoRoent Small Ti-C System* is designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The subject *CoRoent Small Ti-C System* implants are hollow devices manufactured from Polyetheretherketone (PEEK) Optima LT-1 conforming to ASTM F2026. A commercially pure titanium (CP Ti) coating is plasma sprayed to the superior and inferior surfaces of the device. The implant contains a hollow core or graft aperture which allows for packing of autograft or allograft 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. Pins made of either titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3 or tantalum conforming to ASTM F560 or ISO 13782 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 implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

E. Intended Use

The NuVasive CoRoent Small Ti-C System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Ti-C System is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation; the CoRoent Small interbody devices with lordotic angles of 10° or greater are required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/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 Ti-C 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

Non-clinical testing was performed to demonstrate that the subject *CoRoent Small Ti-C System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic axial compression and torsion per ASTM F2077
- Wear debris testing per ASTM F2077, ASTM F1714 and ASTM F1877
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST-72:2011

The results demonstrate that the subject *CoRoent Small Ti-C System* presents no new worst-case for performance testing, and meets the requirements as outlined in the Agency's guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". For the above reasons, the subject device was found to be substantially equivalent to the predicate devices. No clinical studies were conducted.

H. Conclusions

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