November 13, 2019

NuVasive, Incorporated
Jessica LeBlanc
Senior Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K192582
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 18, 2019
Received: September 19, 2019

Dear Jessica LeBlanc:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K192582

Device Name
NuVasive® CoRoent® Small Interlock™ System

Indications for Use *(Describe)*
The CoRoent Small Interlock System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature 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 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:

Jessica LeBlanc
Senior Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3302

Date Prepared: September 18, 2019

510(k) Number: K192582

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 *CoRoent Small Interlock System* is substantially equivalent to multiple predicate devices. *NuVasive CoRoent Small Interlock System* (K142299) serves as the primary predicate device, the *NuVasive CoRoent Small Interbody System* (K163491) and the *Centinel Spine STALIF C* and *STALIF C-Ti* (K150053) serve as additional predicates, and *NuVasive Archon Anterior Cervical Plate System* (K131025) serves as a reference predicate.

D. Device Description

The NuVasive *CoRoent Small Interlock System* is a standalone anterior cervical interbody device consisting of a PEEK (polyetheretherketone) 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® LT1 conforming to ASTM F2026, titanium alloy conforming to ASTM F136, and tantalum conforming to ASTM F560. The implants are available in a variety of sizes to accommodate anatomical conditions. The *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 supplemental fixation.

The purpose of this 510(k) is to modify the indications for use to include the treatment of multilevel cervical disc degeneration with the subject device without supplemental fixation.

E. Indications for Use

The *CoRoent Small Interlock System* is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature 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 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 *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 as 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 Interlock System* for multilevel use without supplemental fixation. A retrospective clinical study of patients with cervical disc degeneration treated with the subject device was performed. Based on the clinical data, it was determined that the *CoRoent Small Interlock System* used in the treatment of multilevel 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) procedures was performed to support the use of the subject device in the treatment of cervical disc degeneration.

H. Conclusions

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