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

December 14, 2017

Re: K172676
Trade/Device Name: NuVasive® Modulus-C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: November 13, 2017
Received: November 14, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172676

Device Name
NuVasive® Modulus-C Interbody System

Indications for Use *(Describe)*
The NuVasive Modulus-C Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Modulus-C 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)

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:

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

Date Prepared: November 9, 2017

B. Device Name

Trade or Proprietary Name:	*NuVasive® Modulus-C Interbody 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:	ODP

C. Predicate Devices

The subject *NuVasive Modulus-C Interbody System* is substantially equivalent to the primary predicate device *NuVasive CoRoent® Small Interbody System cleared in K163491*. Additional predicates include *NuVasive Modulus XLIF Interbody System* (K163230), *CoRoent Small Interbody System* (K140003), *NuVasive CoRoent System* (K081611), *NuVasive CoRoent Small Ti-C System* (K162138) and *VariLift® Cervical Interbody Fusion Device* (K120603).

D. Device Description

The subject *NuVasive Modulus-C Interbody System* are interbody implants manufactured from titanium alloy (Ti-6Al-4V ELI) powder conforming to ASTM F3001. The solid and porous structures are simultaneously built using a powder bed fusion method. The hollow core, or graft aperture, allows for packing of graft to aid in the promotion of a solid fusion. Similarly, the macroporous internal lattice structure provides additional space for graft packing. The microporous, textured surface on the superior and inferior ends of the device serves to grip the adjacent vertebrae to resist migration and expulsion of the device. The device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the cervicothoracic spine. The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient.

E. Indications for Use

The NuVasive Modulus-C Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Modulus-C 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

As was established in this submission, the subject *NuVasive Modulus-C 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 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 *NuVasive Modulus-C Interbody System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static Compression (per ASTM F2077)
- Dynamic Compression (per ASTM F2077)
- Static Compression Shear (per ASTM F2077)
- Dynamic Compression Shear (per ASTM F2077)
- Gravimetric and Particulate analysis (ASTM F1714 and F1877)
- Push-out (per ASTM F04-25-02-02 Draft)
- Subsidence (per ASTM F2267)
- Bacterial endotoxin testing (BET) per ANSI/AAMI ST72:2011/(R)2016

The results demonstrate that the subject *NuVasive Modulus-C Interbody System* meets the same criteria as the predicate devices, and the subject device was therefore found to be substantially equivalent to the predicate. No clinical studies were conducted.

H. Conclusions

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