January 12, 2023

NuVasive, Inc.
Meet Vaghani
Lead Specialist, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K223731
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: December 12, 2022
Received: December 13, 2022

Dear Meet Vaghani:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223731

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, or a bone void filler as cleared by FDA for use in intervertebral fusion 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.

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:

Meet Vaghani
Lead Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (860) 597-2984

Date Prepared: December 13, 2022

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 Modulus-C Interbody System cleared in K172676*. Additional predicates include *NuVasive Modulus XLIF Interbody System* (K163230), *CoRoent Small Interbody System* (K140003), *Nuvasive Thoracolumbar Interbody System* (K203714) and *Conduit Cages, Fibergraft BF Putty* (K222276).

D. Device Description

The subject NuVasive Modulus-C Interbody System is designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The NuVasive Modulus-C Interbody System implants are porous, hollow, devices additively manufactured from Grade 23 titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F3001 Class C. Modulus-C has solid and porous structures which 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 body lattice structure provides additional space for graft packing. The microporous, textured surfaces on the superior and inferior ends of the subject device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Mod-C is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the cervical spine.

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, or a bone void filler as cleared by FDA for use in intervertebral fusion to facilitate fusion.

F. Indications for Use Comparison

One of the purposes of this 510(k) is to expand indications for use of the subject NuVasive Modulus-C Interbody System (K172676) to specify use with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. As outlined in K203714, whether using autogenous and/or allogeneic bone grafts or using the proposed bone void filler within the interbody spacers, the intended use of the subject devices does not change compared to the predicate devices: to act as intervertebral body spacers for intervertebral body fusions. This expansion of indication is substantially equivalent to DePuy Conduit Cages cleared in K222276.

G. Technological Comparison

While there are no changes in design\or material of the device however, introduction of change in blasting media introduces new worst case for mechanical performance. The results of mechanical testing according to appropriate recognized standards as outlined in Performance Testing demonstrate that the subject device's performance is substantially equivalent to the legally marketed predicate device.

H. 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:

- Dynamic Compression (per ASTM F2077)
- Dynamic Torsion (per ASTM F2077)
- Gravimetric and Particulate analysis (ASTM F1714 and F1877)

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.

I. Conclusions

Results of non-clinical testing demonstrate that subject device is substantially equivalent to primary predicate device cleared in K172676 and additional predicate cleared in K140003.