



October 6, 2020

NuVasive, Incorporated
Ms. Michelle Cheung
Manager, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K200953

Trade/Device Name: NuVasive® Cohere® Thoracolumbar Interbody System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Regulatory Class: Class II

Product Code: MAX, PHM, OVD

Dated: August 28, 2020

Received: August 31, 2020

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. 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, 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

Indications for Use

510(k) Number (if known)

K200953

Device Name

NuVasive® Cohere® Thoracolumbar Interbody System

Indications for Use (Describe)

The NuVasive Cohere Thoracolumbar Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. When used with or without the Cohere XLIF internal fixation, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Cohere Thoracolumbar Interbody System is intended for use in interbody fusions in the thoracic spine from T1 to T12, at the thoracolumbar junction (T12-L1), and in the lumbar spine from L1 to S1 for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive Cohere Thoracolumbar Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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

Michelle Cheung
Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Email: Mcheung@nuvasive.com
Telephone: 858-909-3360

Date Prepared: August 28, 2020

B. Device Name

Trade Name: *NuVasive[®] Cohere[®] Thoracolumbar Interbody System*
Common or Usual Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Body Fusion Device with Bone Graft

Device Class: Class II
Classification: 21 CFR § 888.3080
Product Code: MAX, PHM, OVD

C. Predicate Devices

The subject *NuVasive[®] Cohere[®] Thoracolumbar Interbody System* is substantially equivalent to the primary predicate device *NuVasive[®] Cohere[®] Thoracolumbar Interbody System* (K181860), and additional predicates *NuVasive[®] CoRoent[®] Thoracolumbar System* (K170962), *NuVasive[®] Modulus XLIF Interbody System* (K192760), *NuVasive MLX – Medial Lateral Expandable Lumbar Interbody System* (K153105), and *NuVasive[®] CoRoent XLR Standalone System* (K100043).

D. Device Description

The *NuVasive Cohere Thoracolumbar Interbody System* comprises of sterile, single use implant grade polyetheretherketone (PEEK) devices, available in varied footprints and heights, designed for supplemental stabilization of the thoracolumbar spinal column in thoracolumbar intervertebral body fusion procedures.

Each device within the *Cohere Thoracolumbar Interbody System* is comprised of a continuous body of PEEK formed into the final product shape with a porous architecture on select faces of the implant. The porous architecture is derived directly from the implant body and is not a sintered or otherwise additive coating. In addition to PEEK, the device assembly may contain two or more radiolucent markers, depending on footprint, to enable visibility under x-ray in vivo.

The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. The device is intended to be used with supplemental spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

An optional single-sided or dual-sided internal fixation plate with bone screw(s) is offered; this is referred to as the AMS XLIF Plate Single-Sided and AMS XLIF Plate Dual-Sided, respectively. The AMS XLIF Plate is placed in the adjacent vertebral body or bodies for additional migration resistance. The AMS XLIF Plates are available in a variety of sizes to suit the individual pathology and anatomical conditions of the patient. The AMS XLIF Plate Single/Dual Sided and bone screws are substantially equivalent to the plate and screws cleared in predicate *Modulus XLIF Interbody System* (K192760).

E. Indications for Use

The *NuVasive Cohere Thoracolumbar Interbody System* is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. When used with or without the Cohere XLIF internal fixation, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *NuVasive Cohere Thoracolumbar Interbody System* is intended for use in interbody fusions in the thoracic spine from T1 to T12, at the thoracolumbar junction (T12-L1), and in the lumbar spine from L1 to S1 for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The *NuVasive Cohere Thoracolumbar Interbody System* can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

F. Technological Characteristics

As was established in this submission, the subject *Cohere Thoracolumbar 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 *Cohere Thoracolumbar Interbody System* is substantially equivalent to other predicate devices. Engineering rationale and the following testing was performed:

- Static Axial Compression (per ASTM F2077)
 - Dynamic Axial Compression (per ASTM F2077)
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- Dynamic Torsion (per ASTM F2077)
- Compressive and Torsional Wear Particulate Analysis (per ASTM F1877)
- Implant subsidence and expulsion analysis
- Screw push-out analysis

The results demonstrate that the subject *Cohere Thoracolumbar 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 *Cohere Thoracolumbar Interbody System* has been shown to be substantially equivalent to legally marketed predicate devices.
