



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Incorporated
Martin Yahiro, M.D.
Director, Medical Affairs
7475 Lusk Boulevard
San Diego, California 92121

March 24, 2016

Re: K153782
Trade/Device Name: NuVasive® Lumbar Interbody Implants
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: December 30, 2015
Received: December 31, 2015

Dear Dr. Yahiro:

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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153782

Device Name

NuVasive® Lumbar Interbody Implants

Indications for Use (Describe)

NuVasive® Lumbar Non-Interfixated Interbody Implants:

The NuVasive Lumbar Non-Interfixated Interbody Implants, including CoRoent System and CoRoent Ti-C System, are indicated for intervertebral body fusion of the spine in skeletally mature patients. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental internal spinal fixation system cleared by the FDA for use in the lumbosacral spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Lumbar Non-Interfixated Interbody Implants (L and XL platforms) are intended for use at either one level or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

NuVasive® Lumbar Interfixated Interbody Implants:

The NuVasive Lumbar Interfixated Interbody Implants, including CoRoent Single Tab System, CoRoent XL-F System, Brigade Standalone System, and Brigade Hyperlordotic System, are indicated for intervertebral body fusion of the spine in skeletally mature patients. The implants are designed for use with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Lumbar Interfixated Interbody Implants are intended for use at either one level or two contiguous levels in the lumbar spine (L2-S1 for Brigade Systems and L2-L5 for CoRoent Single Tab and XL-F) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

CoRoent Single Tab System, CoRoent XL-F System, and Brigade Hyperlordotic System are intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbosacral spine.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”



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:

Martin Yahiro, M.D.
Director, Medical Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 638-5589

Date Prepared: December 30, 2015

B. Device Name

Trade or Proprietary Name: *NuVasive® Lumbar Interbody Implants*
Common or Usual Name: Intervertebral Body Fusion Device
Classification Name: Spinal Intervertebral Body Fixation orthosis

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

C. Predicate Devices

The subject *NuVasive Lumbar Interbody Implants* is substantially equivalent to the primary predicate device the *Stryker Spine AVS® AL and AVS® ALign PEEK Spacers, AVS® PL and AVS® UniLIF PEEK Spacers, AVS® TL PEEK Spacer, AVS® Navigator PEEK Spacer, AVS® ARIA PEEK Spacer, AccuLIF TL and PL Cage, AVS® Anchor-L Spacer, and Aero™ -AL Lumbar Cage System* (K143163) and additional predicate devices, *CoRoent System* (K141665); *CoRoent Ti-C System* (K140319); *CoRoent Single Tab System* (K131723); *CoRoent XL-F System* (K140479); *CoRoent XLR Standalone System* (K100043); and *Brigade Hyperlordotic System* (K123045).

D. Device Description

The subject *NuVasive Lumbar Interbody Implants* are interbody implants manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026. Additionally, *CoRoent Ti-C* implants are PEEK devices with a commercially pure titanium (CP Ti) coating applied to the superior and inferior surfaces of the device. The PEEK devices contain titanium alloy radiographic markers conforming to ASTM F136 or ASTM F1472 or tantalum markers conforming to ASTM 560 or ISO 13782. The device's hollow core or graft aperture allows for packing of graft material to help promote a solid fusion. Small spikes or teeth on each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device.

The interfixated version of the subject *NuVasive Lumbar Interbody Implants* devices are composed of an interbody device manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026, MP35N conforming to ASTM F562, and titanium alloy conforming to ASTM

F136 and ISO 5832-3. The *Lumbar Interfixated Interbody System* implants have four screw holes in the anterior wall of the PEEK implant that allow titanium alloy screws to be placed in the cranial and caudal vertebral bodies or one or two integrated tabs to allow a titanium alloy screw to be placed in the cranial and caudal vertebral bodies. Additionally, implants include titanium alloy radiographic markers conforming to industry recognized standards.

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

E. Indications for Use

NuVasive® Lumbar Non-Interfixated Interbody Implants:

The *NuVasive Lumbar Non-Interfixated Interbody Implants*, including *CoRoent System* and *CoRoent Ti-C System*, are indicated for intervertebral body fusion of the spine in skeletally mature patients. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental internal spinal fixation system cleared by the FDA for use in the lumbosacral spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *Lumbar Non-Interfixated Interbody Implants* (L and XL platforms) are intended for use at either one level or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

NuVasive® Lumbar Interfixated Interbody Implants:

The *NuVasive Lumbar Interfixated Interbody Implants*, including *CoRoent Single Tab System*, *CoRoent XL-F System*, *Brigade Standalone System*, and *Brigade Hyperlordotic System*, are indicated for intervertebral body fusion of the spine in skeletally mature patients. The implants are designed for use with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *Lumbar Interfixated Interbody Implants* are intended for use at either one level or two contiguous levels in the lumbar spine (L2-S1 for *Brigade Systems* and L2-L5 for *CoRoent Single Tab and XL-F*) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

CoRoent Single Tab System, *CoRoent XL-F System*, and *Brigade Hyperlordotic System* are intended to be used with supplemental fixation systems that that are cleared by the FDA for use in the lumbosacral spine.



F. Technological Characteristics

As was established in this submission, the subject *NuVasive Lumbar Interbody Implants* 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

Mechanical performance testing data was provided as part of the previous submissions to establish substantial equivalence for their use in the lumbosacral spine when used with autogenous bone graft: worst case devices included with the subject system were tested and cleared in these predicate 510(k) submissions. The proposed expansion of the indications for use to include the use of allograft does not create a new mechanical worst-case for any of the implants. Since no new device designs and no new worst case sizes are being introduced to the subject *NuVasive Lumbar Interbody Implants*, the previously presented mechanical testing data are sufficient to support the proposed use of allograft with the subject system and does not warrant the need for additional nonclinical testing. Therefore, no new mechanical testing was performed for this 510(k) submission.

A clinical literature review was performed to support the use of the subject device with allogeneic bone graft for interbody fusions of the lumbar spine. Based on the published clinical literature review, it was determined that the *NuVasive Lumbar Interbody Implants* used in the treatment of lumbar degenerative disc disease has a safety and effectiveness profile that is similar to the predicate devices.

The subject *NuVasive Lumbar Interbody Implants* 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 Lumbar Interbody Implants* has been shown to be substantially equivalent to legally marketed predicate devices.
