



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

December 1, 2015

Re: K152943
Trade/Device Name: NuVasive® Foundation-LL System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: October 2, 2015
Received: October 5, 2015

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

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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" (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.

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)

K152943

Device Name

NuVasive® Foundation-LL System

Indications for Use (Describe)

The Foundation-LL System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The Foundation-LL System is intended for use with autograft.

The Foundation-LL System must be used with supplemental internal spinal fixation systems (i.e., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Foundation-LL System.

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:

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

Date Prepared: October 2, 2015

B. Device Name

Trade or Proprietary Name:	<i>NuVasive® Foundation-LL System</i>
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:	OVD

C. Predicate Devices

The subject *NuVasive Foundation-LL System* is substantially equivalent to the following devices:

Primary Predicate

- K151214 – NuVasive ALIF Interfixated System

Additional Predicates

- K123045 – NuVasive Brigade Hyperlordotic System
- K140319 – NuVasive CoRoent Ti-C System
- K073109 - Surgicraft Limited STALIF TT Intervertebral Body Fusion System
- K071795 – NuVasive CoRoent System

D. Device Description

The *NuVasive Foundation-LL System* is an interfixated interbody system manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026, with commercially pure titanium coating conforming to ASTM F1580 and internal screw hole rings made of titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3. The tantalum radiographic markers conform to ASTM F560. The bone screws are made of titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3. The *NuVasive Foundation-LL System* is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The *Foundation-LL System* consists of a PEEK interbody or PEEK interbody with a commercially pure titanium plasma coating, and three (3) titanium alloy bone screws. The *Foundation-LL System* must be used with

supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

E. Indications for Use

The Foundation-LL System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The Foundation-LL System is intended for use with autograft.

The Foundation-LL System must be used with supplemental internal spinal fixation systems (i.e., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Foundation-LL System.

F. Technological Characteristics

As was established in this submission, the subject *Foundation-LL 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, function, and range of sizes.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *Foundation-LL System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic compression testing (axial and shear) per ASTM F2077
- Wear Debris Testing per ASTM F2077, ASTM F1714, ASTM F1877
- Static Push-out Testing per ASTM Work Item Z8423Z
- Subsidence Testing per ASTM 2267
- Screw Push-out Testing

The results of these studies show that the subject *Foundation-LL System* meets or exceeds the performance of the predicate device and does not introduce any new risks; therefore, the system is substantially equivalent to the predicate device.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *Foundation-LL System* has been shown to be substantially equivalent to legally marketed predicate devices.