September 25, 2020

NuVasive, Incorporated
Ms. Daniela Mahan, Esq., RAC
Senior Specialist, Regulatory Affairs
7475 Lusk Blvd
San Diego, California 92121

Re: K201820
Trade/Device Name: NuVasive® Thoracolumbar Interbody Systems: CoRoent Thoracolumbar System, CoRoent XL Interfixated System, Brigade Standalone System and Brigade Hyperlordotic System, Brigade Lateral System, BASE Interfixated Titanium System, Coalesce Thoracolumbar Interbody Fusion System, Cohere Thoracolumbar Interbody System, Modulus XLIF Interbody System, Modulus TLIF Interbody System, 3DP Interfixated ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, PHM
Dated: June 26, 2020
Received: July 1, 2020

Dear Ms. Mahan:

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 L. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201820

Device Name
CoRoent Thoracolumbar System

Indications for Use *(Describe)*
The NuVasive CoRoent Thoracolumbar 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 and supplemental internal spinal fixation systems that are 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 CoRoent Thoracolumbar System (XL platform) implants are intended for use in interbody fusions in the thoracic spine, from T1 to T12, and at the thoracolumbar junction (T12-L1), and the CoRoent Thoracolumbar System (XL and L platforms) implants are intended for use 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 CoRoent Thoracolumbar System (XL and L platforms) can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K201820

Device Name
CoRoent XL Interfixated System

Indications for Use *(Describe)*
The NuVasive CoRoent XL Interfixated System implants are 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 and supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The devices are to be used in patients who have had at least six months of non-operative treatment.
The NuVasive CoRoent XL Interfixated System implants are intended for use in interbody fusions in the lumbar spine, from L2 to L5, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive CoRoent XL Interfixated System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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510(k) Number *(if known)*
K201820

Device Name
Brigade Standalone System and Brigade Hyperlordotic System

Indications for Use *(Describe)*

The Brigade System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade Standalone System (lordotic angles of 8° and 12°) is a standalone system. The Brigade Hyperlordotic System (lordotic angles of 15° to 30°) must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogeneic 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 Brigade System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade System platform implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the Brigade System platform must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

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)

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510(k) Number *(if known)*
K201820

Device Name
Brigade Lateral System

Indications for Use *(Describe)*
The Brigade Lateral System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade Lateral System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogenic 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 Brigade Lateral System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade Lateral System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K201820

Device Name
BASE Interfixated Titanium System

Indications for Use *(Describe)*

The BASE Interfixated Titanium System is indicated for spinal fusion procedures in skeletally mature patients. The BASE Interfixated Titanium System 10° - 20° lordotic cages may be used as a standalone system. The BASE Interfixated Titanium System 25° - 30° lordotic cages 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. The System is designed for use with autogenous 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 BASE Interfixated Titanium System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The BASE Interfixated System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the BASE Interfixated Titanium System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K201820

Device Name
Coalesce Thoracolumbar Interbody Fusion System

Indications for Use *(Describe)*
The Coalesce Thoracolumbar Interbody Fusion 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 and supplemental internal 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 Coalesce Thoracolumbar Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use 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 Coalesce Thoracolumbar Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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Indications for Use

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510(k) Number *(if known)*
K201820

Device Name
Cohere Thoracolumbar Interbody System

Indications for Use *(Describe)*
The 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 and supplemental internal 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 Cohere Thoracolumbar Interbody System is intended for use in interbody fusions in the thoracic spine, from T1 to T12, and 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 Cohere Thoracolumbar Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K201820

Device Name
Modulus XLIF Interbody System

Indications for Use *(Describe)*
The NuVasive Modulus XLIF 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 Modulus XLIF internal fixation, the system is intended for use with supplemental spinal fixation system 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 Modulus XLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use 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 Modulus XLIF Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K201820

Device Name
Modulus TLIF Interbody System

Indications for Use *(Describe)*
The NuVasive Modulus TLIF 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 and supplemental internal 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 Modulus TLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use 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 Modulus TLIF Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K201820

Device Name
3DP Interfixated ALIF System

Indications for Use *(Describe)*
The NuVasive 3DP Interfixated ALIF System is indicated for spinal fusion procedures in skeletally mature patients. The 3DP Interfixated ALIF System 10°-20° lordotic cages may be used as a standalone system. The 3DP Interfixated ALIF System 25°-30° lordotic cages must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine. The System is designed for use with autogenous 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 NuVasive 3DP Interfixated ALIF System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The 3DP Interfixated ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the 3DP Interfixated ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

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)

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NUVASIVE

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. Daniela Mahan, Esq., RAC
Sr. Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
(858) 458-2285
Date Prepared: June 26, 2020

B. Device Name

Trade or Proprietary Name: *NuVasive® Thoracolumbar Interbody Systems:*
CoRoent Thoracolumbar System
CoRoent XL Interfixated System
Brigade Standalone System and Brigade Hyperlordotic System
Brigade Lateral System
BASE Interfixated Titanium System
Coalesce Thoracolumbar Interbody Fusion System
Cohere Thoracolumbar Interbody System
Modulus XLIF Interbody System
Modulus TLIF Interbody System
3DP Interfixated ALIF 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: MAX, PHM, OVD

C. Predicate Devices

The subject *NuVasive Thoracolumbar Interbody Systems* is substantially equivalent to the following devices:

Primary Predicate Device:

Product Name	510(k) Number	Date of FDA-Clearance
NuVasive CoRoent Thoracolumbar System	K170962	6/26/2017

Additional Predicate Devices:

Product Name	510(k) Number	Date of FDA-Clearance
CoRoent Thoracolumbar System	K153419	4/13/2016
NuVasive Lumbar Interbody Implants	K161230	8/25/216
Brigade System	K161230	8/25/2016
Brigade Lateral System	K181386	8/24/2018
BASE Interfixated Titanium System	K170592	4/26/2017
Vertera Spine Coalesce Thoracolumbar Interbody Fusion System	K173153	12/6/2017
NuVasive Cohere Thoracolumbar Interbody System	K181860	10/5/2018
NuVasive Cohere Thoracolumbar Interbody System	K193541	3/30/2020
Modulus TLIF Interbody System	K172341	10/26/2017
Modulus XLIF Interbody System	K192760	10/18/2019
3DP Interfixated ALIF System	K193593	3/25/2020

D. Device Description

The *NuVasive Thoracolumbar Interbody Systems* are intervertebral body fusion devices, interfixated and non-interfixated. Implants are manufactured of either PEEK-Optima® LT-1 (Polyether-ether-ketone) conforming to ASTM F2026 or Titanium alloy (Ti6Al4V ELI) conforming to ASTM F136/ISO 5832-3. PEEK implants include radiographic markers made of Titanium (Ti) conforming to ASTM F136/ISO 5832-3 or ASTM F1472, or Tantalum (Ta) conforming to ASTM F560 or ISO 13782. Interfixated implants include Titanium alloy (Ti6Al4V ELI) screws conforming to ASTM F136/ISO 5832-3, and in addition, *CoRoent Thoracolumbar Interfixated* implants include canted coil locking mechanism of Nickel-Cobalt-Chromium-Molybdenum alloy (MP35N) conforming to ASTM F562.

CoRoent Thoracolumbar System

The subject *NuVasive CoRoent Thoracolumbar System* are interbodies manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026 or titanium alloy (Ti-6Al-4V) conforming to ASTM F136. 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 autograft 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 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 internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

NUVASIVE

CoRoent XL Interfixated System and Brigade Hyperlordotic System

The subject *CoRoent Thoracolumbar System (Interfixated) and Brigade Hyperlordotic System* are interbodies manufactured from PEEK-Optima LT-1 conforming to ASTM F2026 PEEK-Optima® LT-1, with radiographic markers manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136, and *CoRoent Thoracolumbar Interfixated* implants include canted coil locking mechanism of Nickel-Cobalt-Chromium-Molybdenum alloy (MP35N) conforming to ASTM F562. The devices all contain integrated screws made of titanium alloy, and include a hollow core or graft aperture which allows for packing of autograft to help promote a solid fusion. The subject implants contain small spikes or teeth on each end of the device, which serve to grip the adjacent vertebrae to resist migration and expulsion.

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 *CoRoent XL-F System* and *Brigade Hyperlordotic System* devices are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

Coalesce Thoracolumbar Interbody Fusion System

The *Vertera Spine Coalesce Thoracolumbar Interbody Fusion 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 *Coalesce 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 tantalum markers, depending on footprint, to enable visibility under x-ray in vivo.

Cohere Thoracolumbar Interbody System

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.

Brigade Standalone System

The *NuVasive Brigade Hyperlordotic System* is an interbody system manufactured from PEEK and titanium alloy conforming to industry recognized standards. The *NuVasive Brigade Hyperlordotic System* is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The *Brigade Hyperlordotic* intervertebral fusion device is a device composed of a PEEK interbody implant containing radiographic titanium alloy markers, and-four (4) titanium alloy bone screws. The subject device components are made from Polyetheretherketone (PEEK OPTIMA LTI) conforming to ASTM F-2026 and titanium alloy (Ti-6A1-4V ELI) conforming to ASTM F136 and 150 5832-3.

Brigade Lateral System

The *NuVasive® Brigade® Lateral System* is an interfixated interbody system manufactured from PEEK and titanium alloy conforming to industry recognized standards. The *NuVasive Brigade Lateral System* is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The *Brigade Lateral System* intervertebral fusion device is composed of a PEEK interbody implant containing radiographic titanium alloy markers, and two (2) titanium alloy bone screws. The subject device components are made from Polyetheretherketone (PEEK-OPTIMAL LT1) conforming to ASTM F2026 and titanium alloy (Ti-6A-4V ELI) conforming to ASTM F136 and ISO 5832-3 or (Ti-6A-4V) conforming to ASTM F1472.

Base Interfixated Titanium System

The *NuVasive BASE Interfixated Titanium System* is an interfixated interbody system manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3. The *NuVasive BASE Interfixated Titanium System* is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The *BASE Interfixated Titanium System* consists of a titanium alloy interbody and three (3) titanium alloy bone screws. The *BASE Interfixated Titanium System* 10° – 20° lordotic cages may be used as a standalone system. The *BASE Interfixated Titanium System* 25° - 30° lordotic cages 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.

Modulus XLIF

The subject NuVasive Modulus XLIF 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 thoracolumbar spine.

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.

Modulus TLIF

The subject NuVasive Modulus TLIF 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 thoracolumbar spine.

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 thoracolumbar spine.

3DP Interfixated ALIF System

The subject *NuVasive 3DP Interfixated 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 of the device. The implants are available in a variety sizes and lordotic angles to suit the individual pathology and anatomical conditions of the patient. The *3DP Interfixated ALIF System* 10°-20° lordotic cages may be used as a standalone system. The *3DP Interfixated ALIF System* 25° - 30° lordotic cages must be used with supplemental internal spinal fixation systems (e.g. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

E. Indications for Use

1) *CoRoent Thoracolumbar System*:

The NuVasive CoRoent Thoracolumbar 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 and supplemental internal spinal fixation systems that are 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 CoRoent Thoracolumbar System (XL platform) implants are intended for use in interbody fusions in the thoracic spine, from T1 to T12, and at the thoracolumbar junction (T12-L1), and the CoRoent Thoracolumbar System (XL and L platforms) implants are intended for use 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 CoRoent Thoracolumbar System (XL and L platforms) can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

2) *CoRoent XL Interfixated System*:
The NuVasive CoRoent XL Interfixated System implants are 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 and supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The devices are to be used in patients who have had at least six months of non-operative treatment.
The NuVasive CoRoent XL Interfixated System implants are intended for use in interbody fusions in the lumbar spine, from L2 to L5, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive CoRoent XL Interfixated System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

3) Brigade Standalone System and Brigade Hyperlordotic System
The Brigade System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade Standalone System (lordotic angles of 8° and 12°) is a standalone system. The Brigade Hyperlordotic System (lordotic angles of 15° to 30°) must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogeneic 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 Brigade System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade System platform implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels and for patients with

degenerative spondylolisthesis, the Brigade System platform must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

4) Brigade Lateral System

The Brigade Lateral System is indicated for spinal fusion procedures in skeletally mature patients. The Brigade Lateral System must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The System is designed for use with autogenous and/or allogenic 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 Brigade Lateral System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Brigade Lateral System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

5) BASE Titanium Interfixated System

The BASE Interfixated Titanium System is indicated for spinal fusion procedures in skeletally mature patients. The BASE Interfixated Titanium System 10° - 20° lordotic cages may be used as a standalone system. The BASE Interfixated Titanium System 25° - 30° lordotic cages 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. The System is designed for use with autogenous 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 BASE Interfixated Titanium System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The BASE Interfixated System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the BASE Interfixated Titanium System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

6) Coalesce Thoracolumbar Interbody Fusion System

The Vertera Spine Coalesce Thoracolumbar Interbody Fusion 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 and supplemental internal 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 Vertera Spine Coalesce Thoracolumbar Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use 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 Vertera Spine Coalesce Thoracolumbar Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

7) Cohere Thoracolumbar Interbody Systems

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 and supplemental internal 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, and 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 and sagittal deformity.

8) Modulus XLIF Interbody System

The NuVasive Modulus XLIF 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 Modulus XLIF internal fixation, the system is intended for use with supplemental spinal fixation system 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 Modulus XLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use 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 Modulus XLIF Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

9) Modulus TLIF Interbody System

The NuVasive Modulus TLIF 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 and supplemental internal 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 Modulus TLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use 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 Modulus TLIF Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

10) 3DP Interfixated ALIF System

The NuVasive 3DP Interfixated ALIF System is indicated for spinal fusion procedures in skeletally mature patients. The 3DP Interfixated ALIF System 10°-20° lordotic cages may be used as a standalone system. The 3DP Interfixated ALIF System 25°-30° lordotic cages must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine. The 3DP Interfixated ALIF System used with less than 3 bolts must be used with supplemental internal spinal fixation systems (e.g., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine. The System is designed for use with autogenous 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 NuVasive 3DP Interfixated ALIF System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The 3DP Interfixated ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the 3DP Interfixated ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Thoracolumbar Interbody Systems* are 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. This device does not contain software or electrical equipment.

G. Performance Data

The purpose of the submission is to expand indications to include the treatment of multilevel sagittal deformity in the thoracolumbar spine. A clinical literature analysis of thoracolumbar sagittal deformities treated with the subject device was performed. Based on the clinical data, it was determined that the *NuVasive Thoracolumbar Interbody Systems* used in the treatment of thoracolumbar sagittal deformities has a safety and effectiveness profile similar to the predicate device.

No new *NuVasive Thoracolumbar Interbody Systems* implant designs are being introduced to the previously cleared *CoRoent Thoracolumbar System* (K153419, K161230, K170962), *Brigade System* (K161230, K181386), *BASE Interfixated Titanium System* (K170592), *Vertera Spine Coalesce Thoracolumbar Interbody Fusion System* (K173153), *Cohere Thoracolumbar Interbody System* (K181860, K193541), *Modulus Interbody System* (K172341, K192760) and *3DP Interfixated ALIF System* (K193593) implants. Nevertheless, minor design modifications were made to certain devices within the *CoRoent Thoracolumbar System* (K161230), *Coalesce Thoracolumbar Interbody System* (K163506), *Cohere Thoracolumbar Interbody System* (K181860) and *Modulus TLIF Interbody System* (K172341) systems via add-to-file. We include the confirmatory mechanical testing that shows that the minor design modifications do not create a new worst case that would require new or additional testing. Since multilevel sagittal deformity use does not change the biomechanical stresses placed upon the individual implants, additional non-clinical testing is unwarranted. Therefore, no performance testing was performed for this 510(k) submission and the worst case devices included with the subject system were tested and cleared in predicate 510(k) submissions. Only previously cleared devices are the subject of this submission, i.e., there is no new worst case device.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NuVasive Thoracolumbar Interbody Systems* have been shown to be substantially equivalent to legally marketed predicate devices.