December 23, 2021

NuVasive, Incorporated
Martin Yahiro, MD
Director, Medical Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K203714
Trade/Device Name: NuVasive Thoracolumbar Interbody Systems: NuVasive CoRoent Thoracolumbar System, NuVasive CoRoent XL Interfixated System, Brigade System, Brigade Lateral System, BASE Interfixated Titanium System, Coalesce Thoracolumbar Interbody Fusion System, NuVasive Cohere Thoracolumbar Interbody System, NuVasive Modulus XLIF Interbody System, NuVasive Modulus TLIF Interbody System, NuVasive Modulus ALIF System
NuVasive Attrax Putty
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM, OVD, MQV
Dated: December 8, 2021
Received: December 9, 2021

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. 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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K203714

Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

NuVasive 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

NuVasive 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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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# Indications for Use

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*See PRA Statement below.*

510(k) Number *(if known)*
K203714

Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

NuVasive Brigade 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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510(k) Number *(if known)*
K203714

Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

NuVasive 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 bone graft, allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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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510(k) Number *(if known)*
K203714

Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

NuVasive BASE Interfixated Titanium 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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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510(k) Number *(if known)*
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Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

Coalesce Thoracolumbar Interbody Fusion System

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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

NuVasive Cohere Thoracolumbar Interbody System

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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 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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*See PRA Statement below.*

510(k) Number *(if known)*
K203714

Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

NuVasive 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without Modulus XLIF internal fixation, the system is intended 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 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.

NuVasive 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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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# Indications for Use

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Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203714

Device Name
NuVasive Thoracolumbar Interbody Systems and NuVasive Attrax Putty

Indications for Use *(Describe)*

NuVasive Modulus ALIF System

The *NuVasive Modulus ALIF System* is indicated for spinal fusion procedures in skeletally mature patients. The *Modulus ALIF System* 10°-20° lordotic cages may be used as a standalone system. The *Modulus 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *NuVasive Modulus 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 *Modulus 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 *Modulus ALIF Syste*m 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.

NuVasive Attrax Putty

*Attrax Putty* is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, and pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bone structure. *NuVasive Attrax Putty* resorbs and is replaced with bone during the healing process. *NuVasive Attrax Putty* may be used in combination with autogenous bone in the posterolateral spine and pelvis. When used in intervertebral body fusion procedures, *NuVasive Attrax Putty* must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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) 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. Jessica LeBlanc
Manager, Regulatory Affairs
NuVasive, Incorporated
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San Diego, California 92121
(951) 816-0973

Martin Yahiro, M.D.
Director, Medical Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
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(858) 320-4550

Date Prepared: December 21, 2021

**B. Device Name**

Trade or Proprietary Name: *NuVasive Thoracolumbar Interbody Systems*, which includes the following systems:

- *CoRoent Thoracolumbar System*, including *CoRoent Thoracolumbar System* (Non-Interfixated) and *CoRoent XL (Interfixated System*)
- *Brigade System*, including *Brigade Hyperlordotic, Brigade Standalone,* and *Brigade Lateral*
- *BASE Interfixated Titanium System*
- *Coalesce Thoracolumbar Interbody Fusion System*
- *Cohere Thoracolumbar Interbody System*
- *Modulus Interbody System, including Modulus XLIF Interbody System*, *Modulus TLIF Interbody System*, and *Modulus 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 |

| | |
|---|---|
| Trade or Proprietary Name: | *NuVasive Attrax Putty* |
| Common Name: | Bone void filler |
| Classification Name: | Resorbable calcium salt bone void filler device |
| Device Class: | Class II |
| Classification: | 21 CFR 888.3045 |
| Product Code: | MQV |

NUVASIVE

**C. Predicate Devices**

The subject *NuVasive Thoracolumbar Interbody Systems* is substantially equivalent to the primary predicate device *NuVasive Thoracolumbar Interbody Systems* (K201820) and the additional predicate devices, *Modulus XLIF Interbody System* (K201692), and *Cohere Thoracolumbar Interbody System* (K200953).

The subject *NuVasive Attrax Putty* is substantially equivalent to the predicate device, *NuVasive Attrax Putty* (K191974).

DePuy Synthes T-PAL (K100089, K151276) was used as a reference device.

**D. Device Description**

The *NuVasive Thoracolumbar Interbody Systems* is inclusive of several intervertebral body fusion devices, interfixated and non-interfixated. The hollow core, or graft aperture, of the devices allows for packing of graft to aid in the promotion of a solid fusion. The devices are available in varied footprints, heights, and lordotic angles to suit the individual pathology and anatomical conditions of the patient, utilizing placement through various surgical approaches. *NuVasive Attrax Putty* is a synthetic, osteoconductive and resorbable bone void filler device consisting of ceramic granules premixed with a polymeric binder that provides cohesion between the granules. Pressure applied by user manipulation allows the *Attrax Putty* to be molded into specific shapes, mixed with autograft, or contoured into a bone defect or the graft aperture of a spinal interbody implant, as desired by the clinician. The subject implants are offered sterile and/or non- sterile with the accessory surgical instruments packaged as non-sterile to be sterilized by the end user.

The purpose of this submission is to expand the indications for use of the *NuVasive Thoracolumbar Interbody Systems* to include its use with *NuVasive Attrax Putty.*

**E. Indications for Use**

***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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***Brigade System (Brigade Standalone and Brigade Hyperlordotic):***
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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft , or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***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 bone graft, allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***Coalesce Thoracolumbar Interbody Fusion System:***

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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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 and sagittal deformity.

***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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without *Modulus* XLIF internal fixation, the system is intended 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 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.

***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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion 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.

***Modulus ALIF System:***

The *NuVasive Modulus ALIF System* is indicated for spinal fusion procedures in skeletally mature patients. The *Modulus ALIF System* 10°-20° lordotic cages may be used as a standalone system. The *Modulus 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 bone graft, allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The *NuVasive Modulus 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 *Modulus 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 *Modulus 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.

***NuVasive Attrax Putty:***

*Attrax Putty* is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, and pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bone structure. *NuVasive Attrax Putty* resorbs and is replaced with bone during the healing process. *NuVasive Attrax Putty* may be used in combination with autogenous bone in the posterolateral spine and pelvis. When used in intervertebral body

fusion procedures, *NuVasive Attrax Putty* must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

**F. Technological Characteristics**

As was established in this submission, the subject *NuVasive Thoracolumbar Interbody Systems* and *NuVasive Attrax Putty* are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have the same technological characteristics to their predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes. These devices do not contain software or electrical equipment.

**G. Performance Data**

The purpose of this submission is to expand the indications for use of the *NuVasive Thoracolumbar Interbody Systems* to include its use with *NuVasive Attrax Putty.* A clinical outcomes registry study and a clinical literature analysis of patients treated with the subject devices were performed. The registry data provided clinical and radiographic data from 75 patients treated with the *NuVasive Modulus XLIF* Device and *Attrax Putty* and was supplemented by a literature comparison of *NuVasive Attrax Putty* used with another interbody fusion device in the NuVasive Thoracolumbar Interbody System, the *NuVasive CoRoent* (PEEK) device. Comparisons of intervertebral body devices with *Attrax Putty* versus autograft or allograft, and versus posterolateral fusion supported the performance in intervertebral body fusion based on fusion and adverse event rates. Additional clinical and engineering rationale was provided to address technological differences between the intervertebral body fusion devices included in the submission to support use of NuVasive *Attrax Putty* with all the fusion devices in the *NuVasive Thoracolumbar Interbody System.* Bacterial endotoxin testing (BET) is performed for all implant systems per ANSI/AAMI ST72:2011/(R)2016. Based on the clinical data, it was determined that the *NuVasive Thoracolumbar Interbody Systems* filled with *NuVasive Attrax Putty* have a safety and effectiveness profile similar to the predicate devices.

**H. Conclusions**

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