July 11, 2023

NuVasive, Incorporated
Hannah Tan
Regulatory Affairs Specialist
7475 Lusk Boulevard
San Diego, California 92121

Re: K231735
Trade/Device Name: NuVasive CoRoent Small Interbody System; NuVasive CoRoent Small Contoured Interbody System; NuVasive CoRoent Small Interlock System; NuVasive CoRoent Small Interlock II System; NuVasive CoRoent Small Ti-C System; NuVasive Cohere Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: June 12, 2023
Received: June 14, 2023

Dear Hannah Tan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K231735

Device Name

NuVasive CoRoent Small Interbody System;
NuVasive CoRoent Small Contoured Interbody System;
NuVasive CoRoent Small Interlock System;
NuVasive CoRoent Small Interlock II System;
NuVasive CoRoent Small Ti-C System;
NuVasive Cohere Cervical Interbody System

Indications for Use *(Describe)*

NuVasive CoRoent Small Interbody System:
The NuVasive CoRoent Small Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation; the CoRoent SHL interbody device is required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

NuVasive CoRoent Small Contoured Interbody System:
The NuVasive CoRoent Small Contoured Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Contoured Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

NuVasive CoRoent Small Interlock System:
The CoRoent Small Interlock System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with autogenous or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

NuVasive CoRoent Small Interlock II System:
The NuVasive CoRoent Small Interlock II System is an anterior cervical interbody fusion system

indicated for use in skeletally mature patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The CoRoent Small Interlock II System (lordotic angles of 7° to 15°) is a standalone system. The CoRoent Small Interlock II System (lordotic angles of 20° to 30°) must be used with supplemental fixation cleared by the FDA. The System is intended to be used with autogenous or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to or a bone void filler as cleared by the FDA for use in intervertebral body fusion facilitate fusion. The cervical devices are to be used in patient who have had at least six weeks of non-operative treatment.

NuVasive CoRoent Small Ti-C System:
The NuVasive CoRoent Small Ti-C System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Ti-C System is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation; the CoRoent Small interbody devices with lordotic angles of 10° or greater are required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

NuVasive Cohere Cervical Interbody System:
The Cohere® Cervical Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Vertera Spine Cohere Cervical Interbody Fusion Device is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary**

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

**A. Submitted by:**

Hannah Tan

Specialist, Regulatory Affairs

NuVasive, Incorporated

7475 Lusk Blvd.

San Diego, California 92121

Telephone: (707) 696-5075

Date Prepared: July 7, 2023

**B. Device Name**

Trade or Proprietary Name:

*NuVasive CoRoent Small Interbody System*

*NuVasive CoRoent Small Contoured Interbody System*

*NuVasive CoRoent Small Interlock System*

*NuVasive CoRoent Small Interlock II System*

*NuVasive CoRoent Small Ti-C System*

*NuVasive Cohere Cervical Interbody System*

Common or Usual Name: Intervertebral Fusion Device with Bone Graft, Cervical

Classification Name: Intervertebral Body Fusion Device

Device Class: Class II

Classification: 21 CFR § 888.3080

Product Code: ODP, OVE

**C. Predicate Devices**

The subjects *NuVasive CoRoent Small Interbody System, NuVasive CoRoent Small Contoured Interbody System, NuVasive CoRoent Small Interlock System, NuVasive CoRoent Small Interlock*

*II System, NuVasive CoRoent Small Ti-C System, NuVasive Cohere Cervical Interbody System* are substantially equivalent to the primary predicate devices *NuVasive Modulus-C Interbody System, NuVasive CoRoent Small Interbody System, NuVasive CoRoent Small Contoured Interbody System, NuVasive CoRoent Small Interlock System, NuVasive CoRoent Small Interlock II System, NuVasive Small Ti-C System, and NuVasive Cohere Cervical Interbody System* cleared in K223731, K163491, K142050, K192582, K170961, K162138, and K173030 respectively.

**D. Device Description**

**NuVasive CoRoent Small Interbody System:**

The NuVasive CoRoent Small Interbody System is designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The CoRoent Small Interbody System implants are hollow devices manufactured from polyetheretherketone (PEEK) Optima LT-1 conforming to ASTM F2026. The hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to help promote a solid fusion. Rows of teeth on the surface of each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Pins made of either titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3 or tantalum conforming to ASTM F560 or ISO 13782 serve as radiopaque markers so the location and orientation of the device may be seen radiographically during and after the procedure for position confirmation. The CoRoent Small Interbody System and accessory surgical instruments will be packaged and provided both sterile and non-sterile. The non-sterile implants are designed to be sterilized by the user before each use. The implantation technique does not differ from that performed for the predicate CoRoent Small offerings cleared in NuVasive CoRoent Small Interbody System (K163491). The CoRoent Small Interbody offerings are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the cervical spine. The CoRoent Small Hyperlordotic offerings (lordotic angles of 10° to 30°) must be used with an anterior cervical plate. The CoRoent Small Interbody System is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The only difference is the expansion of

indications to include use with a bone void filler as cleared by the FDA for use in intervertebral body fusion.

**NuVasive CoRoent Small Contoured Interbody System:**

The NuVasive® CoRoent® Small Contoured Interbody System is designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The CoRoent Small Contoured Interbody System implants are hollow devices manufactured from Polyetheretherketone (PEEK) Optima LT-1 conforming to ASTM F2026. The hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to help promote a solid fusion. Rows of teeth on the surface of each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Pins made of either titanium alloy (Ti-6Al-4V) or tantalum serve as radiopaque markers allowing the location and orientation of the device to be seen radiographically during and after the procedure for position confirmation. Both the subject device and its accessory surgical instruments will be packaged and initially provided non-sterile and are designed to be sterilized by the user before each use. The implantation technique for the subject CoRoent Small Contoured Interbody System does not differ from that performed for the predicate CoRoent Small offerings cleared in CoRoent Small Interbody System (K163491). The CoRoent Small Interbody offerings are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the cervical spine. The CoRoent Small Contoured Interbody System is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The only difference is the expansion of indications to include use with a bone void filler as cleared by the FDA for use in intervertebral body fusion and to expand indications to include treatment of degenerative disc disease (DDD) of the cervical spine at multiple contiguous levels.

**NuVasive CoRoent Small Interlock System:**

The NuVasive CoRoent Small Interlock System is a standalone intervertebral body fusion device that consists of various sizes of PEEK implants with titanium alloy or tantalum radiographic markers, titanium alloy washers and bone screws, and associated general instruments. The implants are manufactured from polyetheretherketone PEEK-OPTIMA® LT1 conforming to ASTM F2026, with titanium alloy washers and bone screws conforming to ASTM F136, ASTM F1472 or ISO 5832-3. The hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to help promote a solid fusion. Rows of teeth on the surface of each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Pins made of either titanium alloy (Ti-6Al-4V) or tantalum serve as radiopaque markers so the location and orientation of the device may be seen radiographically during and after the procedure for position confirmation. The NuVasive CoRoent Small Interlock System is designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The CoRoent Small Interlock offerings are intended to be standalone without supplemental fixation. ThThe CoRoent Small Interlock System implants will be packaged either sterile or non-sterile while accessory surgical instruments will be provided non-sterile and are designed to be sterilized by the user before each use. The implantation technique does not differ from that described in primary predicate CoRoent Small Interlock System (K192582). The CoRoent Small Interlock System is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The only difference is the expansion of indications to include use with a bone void filler as cleared by the FDA for use in intervertebral body fusion.

**NuVasive CoRoent Small Interlock II System:**

The NuVasive CoRoent Small Interlock II System is an intervertebral body fusion device designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The System consists of various sizes of PEEK implants with tantalum radiographic markers, titanium alloy washers and bone screws. Additionally, a commercially

pure titanium (CP Ti) coating is plasma sprayed to the superior and inferior surfaces of the interbody device. The implants are manufactured from Polyetheretherketone PEEKOPTIMA® LT1 conforming to ASTM F2026, commercially pure titanium coating conforming to ASTM F1580, with titanium alloy washers and bone screws conforming to ASTM F136, ASTM F1472 or ISO 5832-3. The hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to help promote a solid fusion. Rows of teeth on the surface of each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Pins made of tantalum serve as radiopaque markers so the location and orientation of the device may be seen radiographically during and after the procedure for position confirmation. The implantation technique for the subject CoRoent Small Interlock II implants (including hyperlordotic offerings) does not differ from that performed for the predicate Interlock offerings cleared in CoRoent Small Interlock System (K192582). Both the subject PEEK only interbodies, screws and accessory surgical instruments will be packaged and initially provided non-sterile and are designed to be sterilized by the user before each use. Additionally, the subject PEEK with CP Ti coating implants will be provided sterile. Non-clinical testing demonstrates that the subject device meets performance requirements set by the Agency's guidance document and is substantially equivalent to the predicate NuVasive CoRoent Small Interlock II System (K170961) NuVasive CoRoent Small Interlock System (K192582), and other predicate devices cleared by the Agency. The CoRoent Small Interlock II System is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The only difference is the expansion of indications to include use with a bone void filler as cleared by the FDA for use in intervertebral body fusion and to expand indications to include treatment of degenerative disc disease (DDD) of the cervical spine at multiple contiguous levels.

**NuVasive CoRoent Small Ti-C System:**

The NuVasive CoRoent Small Ti-C System is designed to address cervical pathologies utilizing interbody placement through an anterior surgical approach. The subject CoRoent Small Ti-C System implants are hollow devices manufactured from Polyetheretherketone (PEEK) Optima

LT-1 conforming to ASTM F2026. A commercially pure titanium (CP Ti) coating is plasma sprayed to the superior and inferior surfaces of the device. The hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to help promote a solid fusion. Rows of teeth on the surface of each end of the device serve to grip the adjacent vertebrae to resist migration and expulsion of the device. Pins made of either titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3 or tantalum conforming to ASTM F560 or ISO 13782 serve as radiopaque markers so the location and orientation of the device may be seen radiographically during and after the procedure for position confirmation. The CoRoent Small Ti-C System includes several variants within its offering. Within the subject system, the CoRoent Small Interbody offerings are intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the cervical spine. The CoRoent Small Hyperlordotic offerings (lordotic angles of 10° to 30°) must be used with an anterior cervical plate. The CoRoent Small Ti-C System is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The only difference is the expansion of indications to include use with a bone void filler as cleared by the FDA for use in intervertebral body fusion and to expand indications to include treatment of degenerative disc disease (DDD) of the cervical spine at multiple contiguous levels. Overall, the subject NuVasive CoRoent Small Ti-C System device is substantially equivalent to predicates NuVasive CoRoent Small Interbody System (K163491), and NuVasive Ti-C System (K162138), as well as other predicate devices cleared by the Agency. The CoRoent Small Ti-C System will be provided sterile while its accessory general surgical instruments will be provided non-sterile and designed to be sterilized by the user before each use. The implantation technique does not differ from that performed for the predicate devices cleared in NuVasive CoRoent Small Interbody System (K163491).

**NuVasive Cohere Cervical Interbody System:**

The subject Cohere® Cervical Interbody Fusion Device (K173030) is an interbody fusion device comprised of a single, continuous piece of PEEK Scoria®, which is formed into a final product

shape. The subject device remains solid with an extruded porous layer on the superior and inferior surfaces of the implant body. The porous surface is derived directly from the implant body and is not a sintered or otherwise additive coating. The hollow core or graft aperture allows for packing of autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to help promote a solid fusion. The PEEK cage contains two marker bands made of tantalum R05200 conforming to ASTM F560, which serve as radiopaque markers so the location and orientation of the device may be seen radiographically, during and after the procedure for position confirmation. The Cohere Cervical Interbody Fusion Device comes in a variety of sizes and geometries to suit the individual pathology and anatomical conditions of the patient. The devices are provided sterile, with the accessory surgical instruments packaged as non-sterile to be sterilized by the end user. All accessory instruments utilized with the subject system are the same as those referenced in K173030. A complete part number list of the Cohere Cervical Interbody Fusion Device implants is provided in this submission. This part number list is identical to the list submitted in K173030. The Cohere Cervical Interbody Fusion Device is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The Cohere Cervical Interbody System is identical to the primary predicate with respect to design, footprint, material composition, mechanical performance, labeling, intended use, and sterilization. The only difference is the expansion of indications to include use with a bone void filler as cleared by the FDA for use in intervertebral body fusion.

**E. Indications for Use**

**NuVasive CoRoent Small Interbody System:**

The NuVasive CoRoent Small Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation; the CoRoent SHL interbody device is required

to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

**NuVasive CoRoent Small Contoured Interbody System:**

The NuVasive CoRoent Small Contoured Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Contoured Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

**NuVasive CoRoent Small Interlock System:**

The CoRoent Small Interlock System is a standalone anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with autogenous or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

**NuVasive CoRoent Small Interlock II System:**

The NuVasive CoRoent Small Interlock II System is an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The CoRoent Small Interlock II System (lordotic angles of 7° to 15°) is a standalone system. The CoRoent Small Interlock II System (lordotic angles of 20° to 30°) must be used with supplemental fixation cleared by the FDA. The System is intended to be used with autogenous or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to or a bone void filler as cleared by the FDA for use in intervertebral body fusion facilitate fusion. The cervical devices are to be used in patient who have had at least six weeks of non-operative treatment.

**NuVasive CoRoent Small Ti-C System:**

The NuVasive CoRoent Small Ti-C System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The CoRoent Small Ti-C System is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation; the CoRoent Small interbody devices with lordotic angles of 10° or greater are required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

**NuVasive Cohere Cervical Interbody System:**

The Cohere® Cervical Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Vertera Spine Cohere Cervical Interbody Fusion Device

is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft or a bone void filler as cleared by the FDA for use in intervertebral body fusion to facilitate fusion.

**F. Indications for Use Comparison**

One of the purposes of this 510(k) is to expand indications for use of the subject NuVasive Cervical Interbody Systems to specify use with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. As outlined in K203714, whether using autogenous and/or allogeneic bone grafts or using the proposed bone void filler within the interbody spacers, the intended use of the subject devices does not change compared to the predicate devices: to act as intervertebral body spacers for intervertebral body fusions. This expansion of indications is substantially equivalent to NuVasive Modulus-C Interbody System cleared in K223731.

Another purpose of this 510(k) is to expand indications for use to include treatment of degenerative disc disease (DDD) of the cervical spine at multiple contiguous levels for NuVasive CoRoent Small Contoured Interbody System, NuVasive Small Interlock II System, and NuVasive Small Ti-C System. The predicate K192582 was cleared to expand indications for use to include treatment of degenerative disc disease (DDD) of the cervical spine at multiple contiguous levels for NuVasive CoRoent Small Interlock System.

Subject devices were shown to be substantially equivalent in intended use to predicate devices.

**G. Technological Comparison**

The subject NuVasive CoRoent Small Interbody System, NuVasive CoRoent Small Contoured Interbody System, NuVasive CoRoent Small Interlock System, NuVasive CoRoent Small Interlock II System, NuVasive Small Ti-C System, and NuVasive Cohere Cervical Interbody System devices are substantially equivalent to the legally marketed predicate devices cleared by

the FDA for commercial distribution in the United States. There have been no changes to the design of the subject devices. The subject devices were shown to be substantially equivalent and have the same technological characteristics as the predicate devices through comparison of design, dimensions, material composition, and function.

**H. Non-Clinical and/or Clinical Tests Summary and Conclusions**

The subject NuVasive Cervical Interbody System implants are equivalent in design, geometry, and performance characteristics as those cleared in predicate NuVasive Modulus-C Interbody System, NuVasive CoRoent Small Interbody System, NuVasive CoRoent Small Contoured Interbody System, NuVasive CoRoent Small Interlock System, NuVasive CoRoent Small Interlock II System, NuVasive Small Ti-C System, and NuVasive Cohere Cervical Interbody System (K223731, K163491, K142050, K192582, K170961, K162138, and K173030). Worst case devices included with the subject systems were tested and cleared in predicate 510(k) submissions. The present submission proposes to expand indications for use to specify use with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and to expand the indications for use to include multiple contiguous levels. These changes do not alter any properties relating to performance characteristics or design. Therefore, no performance testing was performed for this Special 510(k) submission.