May 9, 2026

Carlsmed, Inc.
Stephanie Crossman
Regulatory Affairs Specialist
1800 Aston Ave. Suite 100
Carlsbad, California 92008

Re: K260385
Trade/Device Name: aprevo® anterior and lateral lumbar interbody system; aprevo® posterior and transforaminal lumbar interbody system; aprevo® cervical interbody system; corra™ cervical plating system
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP, OVE, OVD, KWQ
Dated: April 10, 2026
Received: April 10, 2026

Dear Stephanie Crossman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260385

Device Name
aprevo® anterior and lateral lumbar interbody system; aprevo® posterior and transforaminal lumbar interbody system; aprevo® cervical interbody System; corra™ cervical plating system

Indications for Use *(Describe)*

aprevo® anterior and lateral lumbar interbody system
aprevo® ALIF and LLIF interbody systems

The aprevo® ALIF and LLIF interbody systems are intended for interbody fusion in skeletally mature patients and are to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® ALIF and LLIF interbody systems are indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These devices may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

The aprevo® ALIF and LLIF interbody systems are indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. The aprevo® ALIF and LLIF interbody systems are to be filled with autograft bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems). These devices may be implanted via a variety of open or minimally invasive approaches.

aprevo® ALIF-X interbody system

The aprevo® ALIF-X interbody system is intended for interbody fusion in skeletally mature patients. The aprevo® ALIF-X interbody system is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous bone and/or corticocancellous bone and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The device may be implanted via an open or minimally invasive approach.

The aprevo® ALIF-X interbody system is indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis, kyphosis, or sagittal), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. The aprevo® ALIF-X interbody system is intended for standalone use at one or two levels of the spine when used with the screws that accompany the implant and with implants less than or equal to 20° of lordosis. At more than two levels or with implants greater than 20° of lordosis, the aprevo® ALIF-X interbody system is intended to be used with the screws that accompany the implant and with supplemental fixation. When used at more than one level in patients with degenerative scoliosis and/or sagittal deformity, the aprevo® ALIF-X interbody system must be used with the screws that accompany the implant and with supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine. These patients should be skeletally mature and have had at least six months of non-operative treatment. The device is to be filled with autograft bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. The device may be implanted via an open or minimally invasive approach.

aprevo® posterior and transforaminal lumbar interbody system
The aprevo® posterior and transforaminal lumbar interbody system is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® posterior and transforaminal lumbar interbody system is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft. The device may be implanted via an open or minimally invasive approach.

The aprevo® posterior and transforaminal lumbar interbody system is indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. The aprevo® posterior and transforaminal lumbar interbody system is to be filled with autograft bone and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone. The device is intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems). The device may be implanted via an open or minimally invasive approach.

aprevo® cervical interbody system
aprevo® cervical ACDF interbody system
The aprevo® cervical ACDF interbody system includes interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The devices are to be filled with autograft bone and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone. The aprevo® cervical ACDF interbody system must be used with supplemental fixation (e.g., cervical plate or cervical posterior fixation).

aprevo® cervical ACDF-X interbody system
The aprevo® cervical ACDF-X interbody system includes interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The devices are to be filled with autograft bone and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone. . When used with the screws that accompany the device, the aprevo® cervical ACDF-X interbody system is intended for use as a standalone system. Deformity procedures to correct coronal angulation or use of a hyperlordotic device (>20° lordosis) must include supplemental fixation (e.g., cervical plate or cervical posterior fixation).

corra™ cervical plating system
The corra™ cervical plating system is intended for anterior cervical fixation (C2-T1) for the following indications:
• Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
• Spondylolisthesis,
• Trauma (i.e., fracture or dislocation),
• Spinal stenosis,
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
• Tumor,
• Pseudoarthrosis, and
• Failed previous 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

Contact Details

Applicant: Carlsmed, Inc.
Address: 1800 Aston Ave Ste 100
Carlsbad, CA 92008
Phone number: (760) 766-1923

Contact person: Stephanie Crossman
Regulatory Affairs Specialist
scrossman@carlsmed.com

Date prepared: February 5, 2026

Device Name

Trade name: aprevo® anterior and lateral lumbar interbody system
aprevo® posterior and transforaminal lumbar interbody system
aprevo® cervical interbody system
corra™ cervical plating system

Common name: Intervertebral Fusion Device with Bone Graft, Lumbar
Intervertebral Fusion Device with Integrated Fixation, Lumbar
Intervertebral Fusion Device with Bone Graft, Cervical
Intervertebral Fusion Device with Integrated Fixation, Cervical
Appliance, Fixation, Spinal Intervertebral Body

Classification name: Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080); Intervertebral Fusion Device with Integrated Fixation, Lumbar (21 CFR 888.3080); Intervertebral Fusion Device with Bone Graft, Cervical (21 CFR 888.3080); Intervertebral Fusion Device with Integrated Fixation, Cervical (21 CFR 888.3080); Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

Class: II

Product code: MAX, ODP, OVE, OVD, KWQ

Legally Marketed Predicate/Reference Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K250827	ODP, OVE, MAX, OVD	aprevo® anterior lumbar interbody fusion device, aprevo® lateral lumbar interbody fusion device, aprevo® anterior lumbar interbody fusion device with interfixation, aprevo® transforaminal lumbar interbody fusion device, aprevo® TLIF-CA Articulating System; aprevo® Cervical ACDF; aprevo® Cervical ACDF-X; aprevo® Cervical ACDF-X No Cam	Carlsmed, Inc.

510(k) Number	Product Code	Trade Name	Manufacturer
Additional Predicate Device(s)			
K250987	MAX	aprevo® posterior/transforaminal lumbar interbody fusion device	Carlsmed, Inc
K252894	ODP, OVE	aprevo® cervical interbody system	Carlsmed, Inc.
K252611	KWQ	aprevo® cervical plating system	Carlsmed, Inc.

Device Description

aprevo® anterior and lateral lumbar interbody system

The aprevo® anterior and lateral lumbar interbody system, which is comprised of the aprevo® ALIF interbody system, aprevo® LLIF interbody system, and aprevo® ALIF-X interbody system configurations, is designed to stabilize the lumbar spinal column and facilitate fusion. The personalized aprevo® devices incorporate patient-specific features and include an aperture intended for the packing of bone graft. The individualized surgical correction plan and device configurations are developed using patient radiological images.

The aprevo® anterior and lateral lumbar interbody system devices are additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001, and the screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The associated system instruments, which facilitate the placement, adjustment, and removal, if necessary, of the implants, are manufactured from medical-grade materials, such as stainless steels and plastics.

aprevo® posterior and transforaminal lumbar interbody system

The aprevo® posterior and transforaminal lumbar interbody system, which is comprised of aprevo® TLIF-O and PLIF interbody system, aprevo® TLIF-C interbody system, and aprevo® TLIF-CA interbody system configurations, is designed to stabilize the lumbar spinal column and facilitate fusion. The personalized aprevo® devices incorporate patient-specific features and include an aperture for the packing of bone graft. The individualized surgical correction plan and device configurations are developed using patient radiological images.

The aprevo® posterior and transforaminal interbody system devices are additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The associated system instruments, which facilitate the placement, adjustment, and removal, if necessary, of the implants, are manufactured from medical-grade materials, such as stainless steels and plastics.

aprevo® cervical interbody system

The aprevo® cervical interbody system, which is comprised of the aprevo® cervical ACDF interbody system and the aprevo® cervical ACDF-X interbody system configurations, is designed to stabilize the cervical spinal column and facilitate fusion. The personalized aprevo® devices incorporate patient-specific features and include an aperture intended for the packing of bone graft. The individualized surgical correction plan and device configurations are developed using patient radiological images.

The aprevo® cervical interbody system interbody devices are additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001, and the screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The associated system instruments, which facilitate the placement, adjustment, and removal, if necessary, of the implants, are manufactured from medical-grade materials, such as stainless steels and plastics.

corra™ *cervical plating system*

The corra™ cervical plating system, which is comprised of the corra™ cervical segmental plating system and the corra™ cervical multilevel plating system configurations, is intended for anterior fixation of the cervical spine. The system consists of a variety of patient-specific segmental and multilevel plates that are additively manufactured from titanium alloy (Ti-4Al-6V ELI) per ASTM F3001 as well as a range of screws manufactured from titanium alloy (Ti-4Al-6V ELI) per ASTM F136. The associated system instruments, which facilitate the placement, adjustment, and removal, if necessary, of the implants, are manufactured from medical-grade materials, such as stainless steels and plastics.

Indications for Use

aprevo® anterior and lateral lumbar interbody system

aprevo® ALIF and LLIF interbody systems

The aprevo® ALIF and LLIF interbody systems are intended for interbody fusion in skeletally mature patients and are to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® ALIF and LLIF interbody systems are indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These devices may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

The aprevo® ALIF and LLIF interbody systems are indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. The aprevo® ALIF and LLIF interbody systems are to be filled with autograft bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems). These devices may be implanted via a variety of open or minimally invasive approaches.

aprevo® ALIF-X interbody system

The aprevo® ALIF-X interbody system is intended for interbody fusion in skeletally mature patients. The aprevo® ALIF-X interbody system is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous bone and/or corticocancellous bone and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The device may be implanted via an open or minimally invasive approach.

The aprevo® ALIF-X interbody system is indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis, kyphosis, or sagittal), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. The aprevo® ALIF-X interbody system is intended for standalone use at one or two levels of the spine when used with the screws that accompany the implant and with implants less than or equal to 20° of lordosis.

At more than two levels or with implants greater than 20° of lordosis, the aprevo® ALIF-X interbody system is intended to be used with the screws that accompany the implant and with supplemental fixation. When used at more than one level in patients with degenerative scoliosis and/or sagittal deformity, the aprevo® ALIF-X interbody system must be used with the screws that accompany the implant and with supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine. These patients should be skeletally mature and have had at least six months of non-operative treatment. The device is to be filled with autograft bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. The device may be implanted via an open or minimally invasive approach.

aprevo® posterior and transforaminal lumbar interbody system

The aprevo® posterior and transforaminal lumbar interbody system is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® posterior and transforaminal lumbar interbody system is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft. The device may be implanted via an open or minimally invasive approach.

The aprevo® posterior and transforaminal lumbar interbody system is indicated for use at one or more levels of the lumbosacral spine as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six months of non-operative treatment. The aprevo® posterior and transforaminal lumbar interbody system is to be filled with autograft bone and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone. The device is intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems). The device may be implanted via an open or minimally invasive approach.

aprevo® cervical interbody system

aprevo® cervical ACDF interbody system

The aprevo® cervical ACDF interbody system includes interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The devices are to be filled with autograft bone and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone. The aprevo® cervical ACDF interbody system must be used with supplemental fixation (e.g., cervical plate or cervical posterior fixation).

aprevo® cervical ACDF-X interbody system

The aprevo® cervical ACDF-X interbody system includes interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The devices are to be filled with autograft

bone and/or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone. When used with the screws that accompany the device, the aprevo® cervical ACDF-X interbody system is intended for use as a standalone system. Deformity procedures to correct coronal angulation or use of a hyperlordotic device (>20° lordosis) must include supplemental fixation (e.g., cervical plate or cervical posterior fixation).

corra™ cervical plating system

The corra™ cervical plating system is intended for anterior cervical fixation (C2-T1) for the following indications:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudoarthrosis, and
- Failed previous fusion.

Summary of Technological Characteristics

The aprevo® interbody systems and corra™ cervical plating system technological characteristics are substantially equivalent to the predicate devices. The equivalence determination was based on comparison of intended use/indications for use and technological characteristics, including operating principle, design and components, materials, manufacturing, biocompatibility, packaging, labeling, sterility, and non-clinical testing. The subject systems differ from the predicate systems in regard to the addition of non-sterile instrument configurations, which do not raise questions of safety and effectiveness as demonstrated through non-clinical testing. The subject non-sterile instruments have the same design, same functions, and same instrument/implant interface as the previously cleared sterile instrument configurations.

Non-Clinical Testing

The aprevo® interbody systems and corra™ cervical plating system demonstrated substantially equivalent performance to the cited predicate devices. Testing performed for the additional non-sterile instrument configurations associated with the subject systems included cleaning in accordance with ISO 17664-1 and ANSI AAMI ST98 and sterilization in accordance with ISO 17665 and ANSI AAMI ST79.

Clinical Testing

Not applicable. The determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusion

The submitted data demonstrates that the subject aprevo® interbody systems and corra™ cervical plating system are substantially equivalent to the cited legally marketed predicate devices.