July 7, 2025

Carlsmed, Inc.
% Karen Liu, RAC
Consultant
Karen Liu Consulting
3268 Governor Drive #129
Carlsbad, California 92122

Re: K250827
Trade/Device Name: 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 Cams
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, OVE, ODP
Dated: March 18, 2025
Received: March 18, 2025

Dear Karen Liu:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250827

Device Name
aprevo® anterior and lateral lumbar interbody fusion devices; aprevo® anterior lumbar interbody fusion device with interfixation; aprevo® transforaminal lumbar interbody fusion device; aprevo® TLIF-CA Articulating System; aprevo® Cervical ACDF System; aprevo® Cervical ACDF-X System; aprevo® Cervical ACDF-X NO CAM System

Indications for Use *(Describe)*

aprevo® anterior and lateral lumbar interbody fusion devices

The aprevo® anterior and lateral lumbar interbody fusion devices 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® anterior and lateral lumbar interbody fusion devices 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 cortico-cancellous bone graft. These implants 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® anterior and lateral lumbar interbody fusion devices 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 (6) months of non-operative treatment. aprevo® anterior and lateral lumbar interbody fusion devices are to be filled with autograft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

aaprevo® transforaminal lumbar interbody fusion device

The aprevo® transforaminal lumbar interbody fusion device 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® transforaminal lumbar interbody fusion device 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 and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches.

The aprevo® transforaminal lumbar interbody fusion device 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 (6) months of non-operative treatment. aprevo® transforaminal lumbar interbody fusion devices are to be filled with auto graft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

aprevo® anterior lumbar interbody fusion device with interfixation

The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) is intended for interbody fusion in

skeletally mature patients. The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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 cleared for use in the lumbar spine. The device may be implanted via an open or minimally invasive approach.

The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® TLIF-C Articulating System
The aprevo® TLIF-C Articulating 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® TLIF-C Articulating 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 and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches.

The aprevo® TLIF-C Articulating 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 (6) months of non-operative treatment. aprevo® TLIF-C Articulating System devices are to be filled with autograft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

aprevo® Cervical ACDF and ACDF-X Systems
aprevo® Cervical ACDF Interbody
The aprevo® Cervical ACDF lnterbody System are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: 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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. The aprevo® Cervical ACDF lnterbody System must be used with supplemental fixation systems. For hyperlordotic corrections (≥20° lordosis), the system must be used with at least an anterior cervical plate as supplemental fixation.

aprevo® Cervical ACDF-X Interbody (with and without CAM)

The aprevo® Cervical ACDF-X lnterbody System are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: 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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. When used as a standalone system, the aprevo® Cervical ACDF-X lnterbody implant with integrated screw fixation is intended for use at multiple contiguous levels, or up to two levels when used in trauma, deformity or failed previous fusions. Deformity procedures to correct coronal angulation or any use of hyperlordotic correction (≥20°) must include supplemental fixation such as posterior cervical screw fixation or anterior plating

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

Submitter's Name:	Carlsmed, Inc.
Submitter's Address:	1800 Aston Ave. Ste 100 Carlsbad, CA 92008
Submitter's Telephone:	760-766-1926
Primary Correspondent/ Prepared By:	Karen Liu, RAC Principal, Karen Liu Consulting 3268 Governor Drive #129 San Diego, CA 92122 858-735-0517 regulatory@carlsmed.com
Date Prepared:	March 13, 2025
Trade or Proprietary Name:	aprevo® anterior and lateral lumbar interbody fusion devices aprevo® transforaminal lumbar interbody fusion device aprevo® anterior lumbar interbody fusion device with interfixation aprevo® TLIF-C Articulating System aprevo® Cervical ACDF, aprevo® Cervical ACDF-X, and aprevo® Cervical ACDF-X (NO CAM) System
Common or Usual 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
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX, OVD, OVE, ODP
Classification Panel:	Orthopedic Devices

Predicate Devices

510(k) Number	Product Code	Device Name	Manufacturer	Predicate Type
K243802	MAX OVD	aprevo® anterior and lateral lumbar interbody fusion devices aprevo® anterior lumbar interbody fusion device with interfixation	Carlsmed, Inc.	Primary
K241332	MAX	aprevo® transforaminal lumbar interbody fusion device	Carlsmed, Inc.	Additional
K241019	MAX	aprevo® TLIF-C Articulating System	Carlsmed, Inc.	Additional
K242260	ODP OVE	aprevo® Cervical ACDF System aprevo® Cervical ACDF-X System aprevo® Cervical ACDF-X (NO CAM) System	Carlsmed, Inc.	Additional

Indications for Use:

aprevo® anterior and lateral lumbar interbody fusion devices:

The aprevo® anterior and lateral lumbar interbody fusion devices 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® anterior and lateral lumbar interbody fusion devices 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 cortico-cancellous bone graft. These implants 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® anterior and lateral lumbar interbody fusion devices 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 (6) months of non-operative treatment. aprevo® anterior and lateral lumbar interbody fusion devices are to be filled with autograft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

aprevo® transforaminal lumbar interbody fusion device:

The aprevo® transforaminal lumbar interbody fusion device 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® transforaminal lumbar interbody fusion device 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 and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches.

The aprevo® transforaminal lumbar interbody fusion device 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 (6) months of non-operative treatment. aprevo® transforaminal lumbar interbody fusion devices are to be filled with auto graft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

aprevo® anterior lumbar interbody fusion device with interfixation:

The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) is intended for interbody fusion in skeletally mature patients. The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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 cleared for use in the lumbar spine. The device may be implanted via an open or minimally invasive approach.

The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® TLIF-C Articulating System:

The aprevo® TLIF-C Articulating 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® TLIF-C Articulating 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 and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches.

The aprevo® TLIF-C Articulating 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 (6) months

of non-operative treatment. aprevo® TLIF-C Articulating System devices are to be filled with autograft bone and/or allogenic bone graft composed 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 implants may be implanted via a variety of open or minimally invasive approaches.

aprevo® Cervical ACDF, aprevo® Cervical ACDF-X, and aprevo® Cervical ACDF-X (NO CAM) System:

aprevo® Cervical ACDF lnterbody
The aprevo® Cervical ACDF lnterbody System are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: 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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. The aprevo® Cervical ACDF lnterbody System must be used with supplemental fixation systems. For hyperlordotic corrections (≥20° lordosis), the system must be used with at least an anterior cervical plate as supplemental fixation.

aprevo® Cervical ACDF-X lnterbody (with and without CAM)
The aprevo® Cervical ACDF-X lnterbody System are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: 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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. When used as a standalone system, the aprevo® Cervical ACDF-X lnterbody implant with integrated screw fixation is intended for use at multiple contiguous levels, or up to two levels when used in trauma, deformity or failed previous fusions. Deformity procedures to correct coronal angulation or any use of hyperlordotic correction (≥20°) must include supplemental fixation such as posterior cervical screw fixation or anterior plating.

Device Description:

The aprevo® Lumbar Intervertebral Body Fusion Devices include ALIF, LLIF, TLIF, ALIF-X and TLIF-CA interbodies. The aprevo® lumbar interbody fusion devices are designed to stabilize the lumbar spinal column and facilitate fusion. The personalized aprevo® device incorporates patient specific features to allow the surgeon to tailor the procedure to the individual needs of the patient and includes an aperture intended for the packing of bone graft. The individualized surgical correction plan and device configurations are developed using patient CT scans. The aprevo® devices are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F3001, while the screws that accompany ALIF-X are machined from material per ASTM F136. The devices are accompanied by an inserter instrument

which facilitates the placement of the interbodies. Both the interbody devices and instruments are provided as single use, sterile-packed product to the end user.

The aprevo® Cervical Intervertebral Body Fusion Devices include ACDF, ACDF-X and ACDF-X no cams. The aprevo® Cervical ACDF System, which includes the aprevo® Cervical ACDF Interbody, aprevo® Cervical ACDF-X Interbody, and the aprevo® Cervical ACDF-X (NO CAM) Interbody are designed to stabilize the cervical spinal column and facilitate fusion. The personalized aprevo® devices incorporate patient-specific features to allow the surgeon to tailor the deformity correction to the individual needs of the patient and include an aperture for the packing of bone graft. The aprevo® Cervical ACDF System interbodies are additively manufactured from Ti-6Al-4V ELI titanium alloy per F3001, while the screws are machined from Ti alloy per ASTM F136. The devices are accompanied by an inserter instrument which facilitates the placement of the interbodies. Both the interbody devices and the instruments are provided to the end-user as single use, sterile-packed products.

The purpose of this 510(k) is to extend the expiration of imaging used to create 3D surgical plans. There have been no changes made to the software used in the surgical planning process.

Performance Testing Summary:

Clinical data was used to evaluate imaging expiration. Expiration dating was validated using statistical analysis (DICE score) with an acceptance criterion of $\geq$0.80. Additionally, the performance was evaluated across key cohorts.

Substantial Equivalence:

The aprevo® lumbar and cervical interbody fusion devices are substantially equivalent to the primary predicate aprevo® ALIF-X (K243802), and additional predicates: aprevo® TLIF (K241332), aprevo® TLIF-C Articulating (K241019), and aprevo® Cervical (K242260).

The technological characteristics of the subject implants were compared to the predicates. The dimensions and design features, such as height, footprint, angulation, screw configurations and inserter configurations of the subject implants are identical to the predicates. The manufacturing is substantially equivalent to the predicates.

Conclusion:

Substantial equivalence was determined by a comparison of intended use, indications for use, technological features, manufacturing methods, raw materials and principle of operation. The aprevo® devices are identical to the predicates in intended use, indications for use, manufacturing, materials, technological features and principles of operation.