



August 12, 2024

Carlsmed, Inc
Karen Liu
VP, Quality and Regulatory
1800 Aston Ave., Ste. 100
Carlsbad, California 92008

Re: K241328

Trade/Device Name: aprevo® Anterior and Lateral Lumbar Interbody Fusion device (ALIF/LLIF);
aprevo® Transforaminal Lumbar Interbody Fusion device (TLIF); aprevo®
Anterior Lumbar Interbody Fusion device with Interfixation (ALIF-X)

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Regulatory Class: Class II

Product Code: MAX, OVD

Dated: July 17, 2024

Received: July 17, 2024

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.

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

Submission Number (if known)

K241328

Device Name

aprevo® Anterior and Lateral Lumbar Interbody Fusion device (ALIF/LLIF);
 aprevo® Transforaminal Lumbar Interbody Fusion device (TLIF);
 aprevo® Anterior Lumbar Interbody Fusion device with Interfixation (ALIF-X)

Indications for Use (Describe)

aprevo® ALIF and LLIF:

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® TLIF:

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 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® ALIF-X:

The aprevo® anterior lumbar interbody fusion device with interfixation (ALIF-X) 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® anterior lumbar interbody fusion device with interfixation 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 devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous bone and/or cortico-cancellous bone. These implants may be implanted via a variety of open or minimally invasive approaches. The aprevo® anterior lumbar interbody fusion device with interfixation is intended to be used with the screws that accompany each implant and with supplemental fixation.

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 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® 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. The aprevo® anterior lumbar interbody fusion device with interfixation is intended to be used with the screws that accompany each implant and with supplemental fixation.

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: Carlsmed, Inc.
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Carlsbad, CA 92008

Official Correspondent: Aly Alvarez
Director, Regulatory Affairs
Carlsmed, Inc.
1800 Aston Ave., Ste. 100
Carlsbad, CA 92008
regulatory@carlsmed.com

Date Prepared: May 10, 2024

Trade Name: aprevo® anterior and lateral lumbar interbody fusion device
aprevo® transforaminal lumbar interbody fusion device
aprevo® anterior lumbar interbody fusion device with
interfixation

Common Name: Intervertebral Fusion Device with Bone Graft, Lumbar
Intervertebral Fusion Device With Integrated Fixation, Lumbar

Classification: Class II
21 CFR §888.3080

Product Code: MAX, OVD

Primary Predicate Device: aprevo® anterior and lateral lumbar interbody fusion device (ALIF/LLIF) (K222082)

Additional Predicate Device: aprevo® transforaminal lumbar interbody fusion device (TLIF) (K222082)

Additional Predicate Device: aprevo® anterior lumbar interbody fusion device with fixation (ALIF-X) (K222009)

Device Description:

The aprevo® anterior, lateral and transforaminal lumbar interbody fusion devices are designed to stabilize the lumbar 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 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 and are provided sterile.

The aprevo® anterior lumbar interbody fusion device with interfixation, (ALIF-X), is designed to stabilize the lumbar 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. 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 and ASTM F136. The aprevo® ALIF-X device has a cavity intended for the packing of bone graft.

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 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® 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 and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The aprevo® anterior lumbar interbody fusion device with interfixation 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 devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous bone and/or cortico-cancellous bone. These implants may be implanted via a variety of open or minimally invasive approaches. The aprevo® anterior lumbar interbody fusion device with interfixation is intended to be used with the screws that accompany each implant and with supplemental fixation.

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 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® 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. The aprevo® anterior lumbar interbody fusion device with interfixation is intended to be used with the screws that accompany each implant and with supplemental fixation.

Substantial Equivalence:

The subject devices were demonstrated to be substantially equivalent to the predicates cited above with respect to indications, design, function, and performance.

Performance Testing:

The following testing have been conducted in order to support substantial equivalence:

- Manufacturing Sensitivity Analyses
- Manufacturing Validation Activities
- Mechanical Testing per ASTM F2077

Conclusion:

The aprevo® anterior and lateral lumbar interbody fusion device (ALIF/LLIF), transforaminal lumbar interbody fusion device (TLIF), and anterior lumbar interbody fusion device with interfixation (ALIF-X) are substantially equivalent to the previously cleared devices with respect to their indications for use, design, function, and performance.