



September 20, 2024

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

Re: K241332

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

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral Body Fusion Device

Regulatory Class: Class II

Product Code: MAX, OVD

Dated: September 6, 2024

Received: September 9, 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.

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,

Katherine D. Kavlock -S

for

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)

K241332

Device Name

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

Indications for Use (Describe)

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.

aprevo® anterior and lateral lumbar interbody fusion devices (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® transforaminal lumbar interbody fusion devices (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.

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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VP Quality and Regulatory
Carlsmed, Inc.
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Date Prepared: September 19, 2024

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

Common Name: Intervertebral fusion device with bone graft, lumbar

Classification: Class II
21 CFR §888.3080

Product Code: MAX, OVD

Primary Predicate Device:
aprevo® anterior lumbar interbody fusion devices with interfixation (K222009)

Additional Predicate Devices:
aprevo® anterior and lateral lumbar interbody fusion devices (K222082)
aprevo® transforaminal lumbar interbody fusion devices (K231140)

Device Description:
The aprevo® Intervertebral Body Fusion Devices include ALIF-X, ALIF, LLIF, TLIF-O, and TLIF-C interbodies. The aprevo® 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.

Indications for Use:

aprevo® anterior lumbar interbody fusion device with interfixation (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.

aprevo® anterior and lateral lumbar interbody fusion devices (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[®] transforaminal lumbar interbody fusion devices (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.

Summary of technological similarities and differences

The subject devices are identical to the predicate devices' intended use, indications for use, dimensions, mechanical properties, raw materials, sterilization method and packaging method.

The difference between the subject devices and the predicate devices is the addition of a new heat treatment process. Parts produced using the new process are equivalent to those of the predicate device.

Substantial Equivalence:

The subject device was demonstrated to be substantially equivalent to the predicates cited above with respect to indications, design, function, and performance. Additionally, the subject device is technologically equivalent to the predicate device.

Discussion of Non-Clinical Testing/Performance Data:

The subject device underwent mechanical performance testing to validate that the performance of the worst-case subject devices is substantially equivalent to the previously cleared predicate devices. A summary of the tested performed in shown in the list below:

- Mechanical testing per ASTM F2077-18
 - Static/Dynamic Compression
 - Static/Dynamic Compression Shear
- Testing per ASTM F3001-14
 - Tensile Testing
 - Microstructure Assessment per ASTM F3001
 - Chemical Composition Assessment per ASTM F3001

The performance testing demonstrated substantial equivalence between the subject and predicate devices. The results of the testing did not identify any new or increased risks associated with the new process.

Conclusion:

The aprevo® Interbody Fusion Devices are substantially equivalent to the previously cleared devices with respect to their indications for use, design, function, and performance.