March 17, 2025

Carlsmed, Inc.
Jesse Albright
Sr. Manager, Regulatory Affairs
1800 Aston Ave., Ste. 100
Carlsbad, California 92008

Re: K243802
Trade/Device Name: aprevo® anterior and lateral lumbar interbody fusion device, aprevo® anterior lumbar interbody fusion device with interfixation
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: February 13, 2025
Received: February 14, 2025

Dear Jesse Albright:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K243802

Device Name
aprevo® anterior and lateral lumbar interbody fusion device, aprevo® anterior lumbar interbody fusion device with interfixation

Indications for Use *(Describe)*

aprevo® anterior and lateral lumbar interbody fusion device:
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® 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. ALIF-X implants are 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, ALIF-X is intended to be used with the screws that accompany each 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 a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

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: 760-766-1926

Correspondent: Jesse Albright
Sr. Manager, Regulatory Affairs
regulatory@carlsmed.com

Date prepared: March 14, 2025

Device Name

Trade name: aprevo® anterior and lateral lumbar interbody fusion device;
aprevo® anterior lumbar interbody fusion device with interfixation

Common name: Intervertebral Body Fusion Device

Classification name: Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080); Intervertebral Fusion Device With Integrated Fixation, Lumbar (21 CFR 888.3080)

Class: 2

Product code: MAX, OVD

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K241477	OVD	aprevo® anterior lumbar interbody fusion device with interfixation	Carlsmed, Inc.
Additional Predicate Device(s)			
K243635	OVD	aprevo® anterior lumbar interbody fusion device with interfixation	Carlsmed, Inc.
K241332	MAX, OVD	aprevo® anterior and lateral lumbar interbody fusion device; aprevo® anterior lumbar interbody fusion device with interfixation; aprevo®	Carlsmed, Inc.

		transforaminal lumbar interbody fusion device	

Device Description

aprevo® anterior and lateral lumbar interbody fusion device

The aprevo® anterior and lateral 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 radiological images.

The aprevo® anterior and lateral lumbar interbody fusion devices are additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 and are provided sterile. The associated instruments, which facilitate the placement, adjustment, and removal, if necessary, of the interbody devices, are manufactured from stainless steel and provided sterile packaged for single use.

aprevo® anterior lumbar interbody fusion device with interfixation

The aprevo® anterior lumbar interbody fusion device with interfixation is 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 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 lumbar interbody fusion device with interfixation is additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 and is provided sterile. The device includes screws that are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and are offered in a range of lengths. The associated instruments, which facilitate the placement, adjustment, and removal, if necessary, of the device, are manufactured from stainless steel and provided sterile packaged for single use.

Indications for Use

aprevo® anterior and lateral lumbar interbody fusion device

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® 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. ALIF-X implants are 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, ALIF-X is intended to be used with the screws that accompany each 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 a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

Summary of Technological Characteristics

The subject devices have identical intended use, indications for use, mechanical properties, raw materials, sterilization, and packaging as the predicate devices. The difference between the subject and predicate devices is the addition of optional configurations. The subject configuration's manufacturing processes are identical to those of the predicate devices, and mechanical testing confirmed that the subject devices have the same mechanical properties as the predicate devices.

Non-Clinical Testing

All necessary testing has been performed to establish substantial equivalence of the subject devices to the predicate devices and demonstrate that the subject devices perform as intended. The performance of the aprevo® anterior and lateral lumbar interbody fusion device and aprevo® anterior lumbar interbody fusion device with interfixation in their final, finished form is supported by the following:

- ASTM F2077
  - Static and dynamic compression
  - Static and dynamic compression shear
- ASTM 3001
  - Tensile testing
  - Microstructure assessment
  - Chemical composition
- Cadaveric validation study

Clinical Testing

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

Conclusion

The subject devices are substantially equivalent to the cited legally-marketed predicates with respect to indications, design, materials, function, operation, and performance. The non-clinical testing performed by Carlsmed demonstrated substantial equivalence to the predicate devices.