January 6, 2026

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

Re: K252894
Trade/Device Name: aprevo® cervical interbody system
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: September 11, 2025
Received: September 11, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252894

Please provide the device trade name(s).

aprevo® cervical interbody system

Please provide your Indications for Use below.

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

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

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Contact Details

Applicant: Carlsmed, Inc.
Address: 1800 Aston Ave Ste 100
Carlsbad, CA 92008
Phone number: (760) 766-1926

Contact person: Jesse Albright
Sr. Manager, Regulatory Affairs
jalbright@carlsmed.com

Date prepared: January 5, 2026

Device Name

Trade name: aprevo® cervical interbody system

Common name: Intervertebral Body Fusion Device

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

Class: II

Product code: ODP, OVE

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K250827	ODP, OVE, MAX, OVD	aprevo® Cervical ACDF System, 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	Carlsmed, Inc.
Additional Predicate Device			
K241846	OVE, ODP	E3D™-C Interbody System	Evolution Spine

Device Description

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

The aprevo® cervical interbody system interbody devices are additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 and provided sterile, and the screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and provided sterile. The associated instruments, which facilitate the placement, adjustment, and removal, if necessary, of the interbody devices, are manufactured from stainless steel per ASTM A564 and provided sterile packaged for single patient use.

Indications for Use

aprevo® cervical ACDF interbody system

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

aprevo® cervical ACDF-X interbody system

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

Summary of Technological Characteristics

The aprevo® cervical interbody system technological characteristics are substantially equivalent to the predicate devices. The equivalence determination was based on comparison of intended use/indications for use, operating principle, design, components, materials, biocompatibility, manufacturing, packaging, labeling, sterility, and non-clinical testing.

Non-Clinical Testing

The aprevo® cervical interbody system demonstrated substantially equivalent mechanical performance to the predicate devices through static and dynamic axial compression, compression shear, and torsion testing (ASTM F2077) as well as subsidence testing (ASTM F2267).

Clinical Testing

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

Conclusion

The submitted data demonstrates that the subject aprevo® cervical interbody system is substantially equivalent to the cited legally marketed predicate devices.