July 9, 2024

Carlsmed, Inc.
Aly Alvarez
Director, Regulatory Affairs
1800 Aston Ave., Ste. 100
Carlsbad, California 92008

Re: K241019
Trade/Device Name: aprevo® TLIF-C Articulating System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 21, 2024
Received: June 24, 2024

Dear Aly Alvarez:

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

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.*

Submission Number *(if known)*

K241019

Device Name

aprevo® TLIF-C Articulating System

Indications for Use *(Describe)*

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.

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.**

# 510(k) Summary

## Contact Information

| | |
|---|---|
| **Name** | Carlsmed, Inc. |
| **Address** | 1800 Aston Ave, Ste 100<br>Carlsbad, CA 92008 |
| **Telephone** | 760-766-1926 |
| **Contact person** | Aly Alvarez<br>Director, Regulatory Affairs<br><br>Carlsmed<br>1800 Aston Ave, Ste 100<br>Carlsbad, CA 92008<br><br>Phone: 619-884-4342<br>Email: regulatory@carlsmed.com |
| **Date prepared** | April 12, 2024 |

## Device Name

| | |
|---|---|
| **Trade or proprietary name** | aprevo® TLIF-C Articulating System |
| **Device classification regulation** | §888.3080 |
| **Common name** | Intervertebral Fusion Device with Bone Graft, Lumbar |
| **Classification** | Class II |
| **Product code** | MAX |
| **Classification panel** | Orthopedic Device |

## Predicate Devices

| 510(k) number | Product code | Trade name | Manufacturer |
|---|---|---|---|
| **Primary predicate** | | | |
| K222082 | MAX | aprevo® anterior and lateral lumbar | Carlsmed, Inc. |
| **Reference predicates** | | | |
| K210542 | MAX | aprevo® Transforaminal IBF | Carlsmed, Inc. |
| K202034 | MAX | aprevo™ | Carlsmed, Inc. |

| | | | |
|---|---|---|---|
| | | Intervertebral Body Fusion Device | |

## Description of the Device

The aprevo® TLIF-C Articulating System devices are designed to stabilize the lumbar spinal column and promote fusion. The personalized aprevo® interbodies 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 aprevo® TLIF-C Articulating interbodies are additively manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001. The devices are accompanied by an inserter instrument which facilitates the placement of the interbodies. Both the interbody devices and instrument are provided as single use, sterile-packed product to the end user.

## Indications for Use

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.

## Technological Characteristics

The aprevo® TLIF-C Articulating System is identical or similar to the predicate devices in comparison to device description, functionality and performance (mechanical testing), intended use/indications for use, surgical technique, and technological characteristics such as operating principle, materials of manufacture, and design.

## Substantial Equivalence

The aprevo® TLIF-C Articulating System is substantially equivalent to the referenced predicates. The products have equivalent mechanical performance and are used to treat the same conditions. Both the aprevo® TLIF-C Articulating System and predicates represent a similar design concept in terms of safety and performance.

## Non-clinical Testing

Non-clinical performance testing performed on the subject aprevo® TLIF-C Articulating System demonstrates substantial equivalence to the predicate device. The following testing was conducted:

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic compression-shear per ASTM F2077
- Subsidence per ASTM F2267, and
- Cadaveric study

All testing demonstrated substantial equivalence between the subject and predicate devices.

## 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.