December 13, 2024

Carlsmed, Inc.
Karen Liu
VP Quality and Regulatory
2535 San Clemente Terrace
Carlsbad, California 92008

Re: K243635
Trade/Device Name: 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
Dated: November 20, 2024
Received: November 25, 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,

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

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

Submission Number *(if known)*

K243635

Device Name

aprevo® anterior lumbar interbody fusion device with interfixation

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. 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 degrees of lordosis. At more than two levels or with implants greater than 20 degrees 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.

510(k) Summary

Submitter's Name:	Carlsmed, Inc.
Submitter's Address:	1800 Aston Ave. Ste 100 Carlsbad, CA 92008
Submitter's Telephone:	760-766-1926
Contact Person:	Karen Liu, VP Quality and Regulatory Carlsmed, Inc. 760-766-1926 regulatory@carlsmed.com
Date Prepared:	December 5, 2024
Trade or Proprietary Name:	aprevo® anterior lumbar interbody fusion device with interfixation
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Orthopedic Devices

Predicate Devices

The predicate devices are summarized in the table below.

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K241477	aprevo® anterior lumbar interbody fusion device with interfixation	Carlsmed, Inc.	Primary
K222270	HEDRON™ IA Lumbar Spacers	Globus Medical Inc.	Additional
K222028	IdentiTi ALIF Standalone	Alphatec	Additional

Device Description

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 includes 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, while the screws are machined from material per ASTM F136. 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. The purpose of this 510(k) is to modify the indications for use of the subject device to include standalone indications.

Indications for Use

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 degrees of lordosis. At more than two levels or with implants greater than 20 degrees 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.

Comparison of Technological Characteristics

The aprevo° anterior lumbar interbody fusion device with Interfixation is substantially equivalent to the primary predicate aprevo° anterior lumbar interbody fusion device with Interfixation (K241477), and additional predicates: IdentiTi™ ALIF Standalone (222082) and Globus HEDRON™ IA Lumbar Spacers.

The technological characteristics of the subject implants were compared to the predicates. The dimensions and design features, such as height, footprint, angulation, screw configurations and inserter configurations of the subject implants are similar to the predicates.

Conclusion

Substantial equivalence was determined by a comparison of intended use, indications for use, technological features, manufacturing methods, raw materials and principle of operation. The ALIF-X device is identical to the predicates in intended use, manufacturing, materials, and principle of operation. The ALIF-X device has similar indications for use and similar technological features to the predicates.