December 3, 2020

Carlsmed, Inc.
℅ Meredith May
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K202034
Trade/Device Name: aprevo™ Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 29, 2020
Received: November 2, 2020

Dear Ms. May:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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 STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 *See PRA Statement on last page.*

510(k) Number *(if known)*
K202034

Device Name
aprevo™ Intervertebral Body Fusion Device

Indications for Use *(Describe)*

The aprevo™ anterior lumbar interbody fusion and aprevo™ 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 lumbar interbody fusion and aprevo™ 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.

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:	4250 Executive Sq., Ste. 200 La Jolla, CA 92037
Submitter's Telephone:	760-205-1195
Contact Person:	Meredith May MS Empirical Testing Corp. 719-337-7579 mmay@empiricaltech.com
Date Summary was Prepared:	29-Oct-2020
Trade or Proprietary Name:	aprevo™ Intervertebral Body Fusion Device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The aprevo™ ALIF and LLIF 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. The individualized surgical correction plan and device configurations are developed using patient CT scans. Aprevo™ devices are additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and have a cavity intended for the packing of bone graft.

INDICATIONS FOR USE

The aprevo™ anterior lumbar interbody fusion and aprevo™ 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 lumbar interbody fusion and aprevo™ 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.

TECHNOLOGICAL CHARACTERISTICS

The aprevo™ Intervertebral Body Fusion Device is made from titanium alloy that conforms to ASTM F3001. The subject and predicate devices have nearly identical technological

characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for use
- Technological characteristics
- Sizes
- Materials of manufacture
- Patient specific adaptable features
- Mechanical functionality

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K191391	HEDRON™ Lumbar Spacers	Globus Medical Inc.	Primary
K182158	UNiD Patient-matched PLIF Cage	Medicrea International S.A.	Additional
K133455	CROSSFUSE II CORONAL TAPER	Pioneer Surgical Technology, Inc.	Additional

PERFORMANCE DATA

The aprevo™ Intervertebral Body Fusion Device has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static compression shear per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compression shear per ASTM F2077
- Subsidence per ASTM F2267
- Cadaver Accuracy Validation and Usability Study
- Inter- and Intradesigner Variability Testing for Segmentation, Planning, and Implant Design

The results of this non-clinical testing show that the mechanical performance of the aprevo™ IBFD is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall indications for use, technology characteristics, and mechanical performance data lead to the conclusion that the aprevo™ Intervertebral Body Fusion Device is substantially equivalent to the predicate device.