June 30, 2021

Carlsmed, Inc.
Karen Liu
VP Quality and Regulatory
4250 Executive Sq., Ste. 675
La Jolla, California 92037

Re: K210542
Trade/Device Name: aprevo™ Transforaminal IBF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 29, 2021
Received: June 30, 2021

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 (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 L. 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: 06/30/2020
*See PRA Statement on last page.*

510(k) Number *(if known)*
K210542

Device Name
aprevo™ Transforaminal IBF

Indications for Use *(Describe)*

The aprevo™ Transforaminal interbody device 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™ Personalized Interbody device 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.

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. 675<br>La Jolla, CA 92037 |
| Submitter's Telephone: | 760-766-1926 |
| Contact Person: | Karen Liu, VP Quality and Regulatory<br>Carlsmed, Inc.<br>760-766-1926<br>regulatory@carlsmed.com |
| Date Summary was Prepared: | 29-Jun-2021 |
| Trade or Proprietary Name: | aprevo™ Transforaminal IBF |
| 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™ Transforaminal IBF, including the aprevo™ transforaminal curved lumbar interbody fusion (TLIF-C) and the aprevo™ transforaminal oblique lumbar interbody fusion (TLIF-O), 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. The aprevo™ devices are manufactured from Titanium Alloy (Ti-6Al-4V) per ASTM F3001. The aprevo™ TLIF-C and aprevo™ TLIF-O devices have a cavity intended for the packing of bone graft.

## INDICATIONS FOR USE

The aprevo™ Transforaminal interbody device 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™ Personalized Interbody device 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.

## TECHNOLOGICAL CHARACTERISTICS

The aprevo™ Transforaminal IBF 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** |
|---|---|---|---|
| K190092 | UNiD Patient-specific 3D printed TLIF cage | Medicrea International | Primary |
| K182158 | UNiD Patient-matched PLIF cage | Medicrea International | Additional |
| K202034 | aprevo™ Intervertebral Body Fusion Device | Carlsmed, Inc. | Additional |

## PERFORMANCE DATA

The aprevo™ Transforaminal IBF 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
- TR-056 Clinical Evaluation of Transforaminal Implant Usability, Fit, and Accuracy

The results of this non-clinical testing show that the mechanical performance of the aprevo™ Transforaminal IBF 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™ Transforaminal IBF is substantially equivalent to the predicate device.