Carlsmed, Inc.
Karen Liu
VP Quality and Regualtory
1800 Aston Ave., Ste 100
Carlsbad, California 92008

December 30, 2022

Re: K222195
Trade/Device Name: aprevo® Digital Workflow
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 29, 2022
Received: November 30, 2022

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,

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222195

Device Name
aprevo® Digital Workflow

Indications for Use *(Describe)*
aprevo® Digital Workflow software is intended to view, store, and manipulate 3-D models to visualize surgical plans for spinal alignment. The device inputs a 3-D spine model which is used by trained, medically knowledgeable design personnel in conjunction with inputs from healthcare professionals to produce 3-D models of spinal correction and anatomical measurements. The device outputs are used by healthcare professionals for placement of surgical implants.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K222195
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. 1800 Aston Avenue Suite 100 Carlsbad, CA 92008 760-766-1926 regulatory@carlsmed.com
Date Summary was Prepared:	11/29/2022
Trade or Proprietary Name:	aprevo® Digital Workflow
Predicate Clearance Numbers and Name	K060950, 3MATIC by MATERIALISE
Common or Usual Name:	System, image processing, radiological
Classification:	Class II per 21 CFR §892.2050
Product Code:	LLZ
Classification Panel:	Radiology

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The aprevo® Digital Workflow is a proprietary software tool that visualizes and provides measurements of a healthcare professional's surgical plan for a spinal alignment. The software is used to input the patient's spine model, then view, store and measure the 3D spine model to create a visual representation of the desired surgical plan. The software is used to export the visualization of the surgical plan along with associated measurements. The Subject Device is operated by trained, medically knowledgeable Carlsmed design personnel while the output is reviewed and approved by a healthcare professional.

INDICATIONS FOR USE

aprevo® Digital Workflow software is intended to view, store, and manipulate 3-D models to visualize surgical plans for spinal alignment. The device inputs a 3-D spine model which is used by trained, medically knowledgeable design personnel in conjunction with inputs from healthcare professionals to produce 3-D models of spinal correction and anatomical measurements. The device outputs are used by healthcare professionals for placement of surgical implants.

TECHNOLOGICAL CHARACTERISTICS

The aprevo® Digital Workflow will replace 510(k) cleared software in the implant design workflow to perform 3D model based surgical planning. The software functionality is equivalent to the predicate device (3Matics, K060950) based on the intended use and technological characteristics, and does not raise any new question of safety and effectiveness.

PERFORMANCE DATA

The Subject Device has been evaluated in accordance with internal software specifications and applicable performance standards through the software development and verification and validation procedures to ensure performance according to specifications, user requirements, and the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* and *Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions*.

In addition, the measuring function of the Subject Device was evaluated in bench testing using *in-silico* phantoms with known values.

CONCLUSION

The overall indications for use and technology characteristics of the aprevo® Digital workflow are similar to the primary predicate device. This leads to the conclusion that the proposed aprevo® Digital workflow is substantially equivalent to its primary predicate from the safety and effectiveness perspective.