Carlsmed, Inc.
Karen Liu
VP Quality and Regulatory
1800 Aston Ave. Suite 100
SAN DIEGO, CALIFORNIA 92008

November 3, 2023

Re: K231955
Trade/Device Name: aprevo® Digital Segmentation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 28, 2023
Received: October 5, 2023

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.

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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.

Submission Number *(if known)*

K231955

Device Name

aprevo® Digital Segmentation

Indications for Use *(Describe)*

aprevo® Digital Segmentation software is intended to be used by trained, medically knowledgeable design personnel to perform digital image segmentation of the spine, primarily lumbar anatomy. The device inputs DICOM images and outputs a 3-D model of the spine.

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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510(K) SUMMARY K231955

Submitter's Name:	Carlsmed, Inc.
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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:	October 31, 2023
Trade or Proprietary Name:	aprevo® Digital Segmentation
Predicate Clearance Numbers and Name	K183105, Mimics Medical
Reference Device Number and Name	K202034 aprevo™ Intervertebral Body Fusion Device K201232 Limbus Contour
Common or Usual Name:	Medical Image Management and Processing System
Classification:	Class II per 21 CFR §892.2050
Product Code:	QIH
Classification Panel:	Radiology

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The device is a software medical device that will use DICOM images as input and provide 3D model of the spine structure. Pre-processing will be performed on the uploaded DICOM files to filter soft tissue and identifying spine. Upon removal of soft tissue and identification of spine structure, the software will utilize an AI-based algorithm to segment the structure and render a 3D model as an output.

INDICATIONS FOR USE

aprevo® Digital Segmentation software is intended to be used by trained, medically knowledgeable design personnel to perform digital image segmentation of the spine, primarily lumbar anatomy. The device inputs DICOM images and outputs a 3-D model of the spine.

TECHNOLOGICAL CHARACTERISTICS

The aprevo® Digital Segmentation will allow the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models. The software functionality is equivalent to the predicate device (Mimics Medical, K183105) from intended use and technological characteristics, and does not raise any new question of safety and effectiveness.

SUBSTANTIAL EQUIVALENCE

The subject device, aprevo® Digital Segmentation is software intended to segment spine bony structure in an automated manner. The device has similar intended use and technological characteristics to its predicate device Mimics Medical. The table below includes detail on comparison between the subject device to its predicate device, Mimics Medical (K183105)

Characteristic	Subject Device	Predicate Device	Differences
Name	**aprevo® Digital Segmentation**	**Mimics Medical**	
Clearance Number	K231955	K183105	
Regulation Number	892.2050	892.2050	Identical
Product Code	QIH	LLZ	Similar: both are Image Processing Systems
Indications For Use	aprevo® Digital Segmentation software is intended to be used by trained, medically knowledgeable design personnel to perform digital image segmentation of the spine, primarily lumbar anatomy. The device inputs DICOM images and outputs a 3-D model of the spine.	Mimics Medical is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. Mimics Medical is also intended for measuring and treatment planning. The Mimics Medical output can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of orthopaedic, maxillofacial and cardiovascular applications. Mimics Medical should be used in conjunction with expert clinical judgment.	Similar. The subject device has a narrower indication for use compared to the predicate device.

Characteristic	Subject Device	Predicate Device	Differences
Technical Characteristics			
Compatible Input File Types	DICOM	DICOM and standard imaging formats (such as RAW, TIFF, BMP and jpeg format)	Similar. The subject device has narrower input file types.
Segmentation Functionality	Automatic Spinal Algorithm	Manual tools, Semi-automatic tools, and automatic algorithms	Similar. Both devices include automated spine segmentation tool.
User Interaction	User cannot review and edit segmentation and 3D models	Contains tools to review and edit segmentation and 3D models	Similar: The output of both devices can be reviewed by the user. While the predicate device has a viewer to review and edit segmentation outputs the subject device output does not include any viewer but its outputs can be reviewed as part of the entire workflow utilizing 3rd party software.
3D Model Generation	The subject device generates a 3D model	The predicate device generates a 3D model	Identical
Export Outputs	The subject device generates an output file.	The predicate device generates an output file.	Identical
Intended User Population	Trained Personnel, Knowledgeable in Medicine	Trained personnel, knowledgeable in medicine	Identical

NON-CLINICAL TESTING

The aprevo® Digital Segmentation 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*.

Independent training and validation datasets were selected to ensure model performance would reflect real clinical performance. Validation datasets represented diversity in populations and equipment.

The software performance was evaluated using an IOU (intersection over union) score for segmentation which exceeded the acceptance criteria of 80%. It was also evaluated for accuracy of vertebral body labeling which exceeded the acceptance criteria of 90% overall, with sensitivity and specificity exceeding 80% each. Additionally, the performance was evaluated across key cohorts.

CLINICAL TESTING

Not applicable.

CONCLUSION

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