Carlsmed, Inc.
Karen Liu
VP Quality and Regulatory
1800 Aston Ave. Suite 100
Carlsbad, CA 92008

December 20, 2024

Re: K242599
Trade/Device Name: aprevo® Digital Planning
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 22, 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,

Jessica Lamb, Ph.D
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242599

Device Name

aprevo® Digital Planning

Indications for Use *(Describe)*

The aprevo® Digital Planning software is intended to be used by trained, medically knowledgeable design personnel to generate surgical plans for skeletally mature patients. The device processes a 3D spine model in conjunction with inputs from healthcare professionals to produce 3D models of spinal corrections and anatomical measurements.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Applicant Contact Information

Company Name	Carlsmed, Inc.
Company Address	1800 Aston Ave, Ste 100 Carlsbad, CA 92008
Company Telephone	760-766-1926
Contact Person	Karen Liu, VP Quality and Regulatory Carlsmed, Inc. 1800 Aston Ave, Ste 100 Carlsbad, CA 92008 Phone: 760-766-1926 Email: regulatory@carlsmed.com
Date Prepared	November 22, 2024

Device Name

Trade or proprietary name	aprevo® Digital Planning
Device classification regulation	§892.2050
Common name	Image processing system
Classification	Class II
Product code	LLZ
Classification panel	Radiology

Predicate Device

510(k) number	Product code	Trade name	Manufacturer
K222195	LLZ	aprevo® Digital Workflow	Carlsmed, Inc.

Description of the Device

The aprevo® Digital Planning, is a rules-based, semi-automated surgical planning software that, based on surgeon input, measures the 3D spine model and results in a spinal correction plan. The outputs consist of a surgical plan and 3D spinal correction assets, which are then reviewed by the surgeon. The device is operated by trained, medically knowledgeable Carlsmed design personnel.

Indications for Use

The aprevo® Digital Planning software is intended to be used by trained, medically knowledgeable design personnel to generate surgical plans for skeletally mature patients. The device processes a 3D spine model in conjunction with inputs from healthcare professionals to produce 3D models of spinal corrections and anatomical measurements.

Technological Characteristics

The aprevo® Digital Planning software offers the option to semi-automatically place landmarking points and apply a series of correctional operations. The aprevo® Digital Planning software is substantially equivalent to the predicate devices through a comparison including the intended use, design, technological characteristics, and functionality.

Substantial Equivalence

The software functionality is equivalent to the predicate device (K222195) based on the intended use and technological characteristics and does not raise any new question of safety and effectiveness. The table below includes details on a comparison between the subject and predicate devices.

Characteristic	Subject Device	Primary Predicate Device	Substantial Equivalence?
Name	**aprevo® Digital Planning**	**aprevo® Digital Workflow**	
Clearance Number	K242599	K222195	
Regulation Number	892.2050	892.2050	Identical
Device Class	II	II	Identical
Product Code	LLZ	LLZ	Identical
Intended Use and Indications for Use	The aprevo® Digital Planning software is intended to be used by trained, medically knowledgeable design personnel to generate surgical plans for skeletally mature patients. The device processes a 3D spine model in conjunction with inputs from healthcare professionals to produce 3D models of spinal corrections and anatomical measurements.	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.	Substantially Equivalent
Technological Characteristics			
Algorithms	• Landmark determination algorithm • Surgical plan generation algorithm	• Landmarking and correction plan generation is manually conducted by operators	Substantially Equivalent
Compatible Input File Types	DICOM	DICOM	Identical
Process Functionality	Semi-automatic landmark and surgical plan generation	Manual landmark and surgical plan generation	Substantially Equivalent
User Interaction	User interaction is that the operator provides the surgical inputs, then initiates the landmarking and surgical plan generation algorithms	User interaction is that the operator must manually place landmarking points and perform a series of operations to create a surgical plan	Substantially Equivalent
Export Outputs	Surgical plan	Surgical plan	Identical
Intended User Population	Internal Carlsmed personnel only	Internal Carlsmed personnel only	Identical

Non-clinical Testing

The aprevo® Digital Planning software has been evaluated in accordance with internal software specifications and applicable performance standards. The surgical plans generated by aprevo® Digital Planning were shown to be substantially equivalent, with 90% confidence and reliability, to plans manually created by medically knowledgeable operators. In addition, the software development, verification and validation procedures ensure that the device performs according to specifications, user requirements, and the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Conclusion

Based on the intended use, indications for use, functions, technological characteristics, performance testing, and comparison to the predicate device, the subject aprevo® Digital Planning device has been shown to be substantially equivalent to the predicate.