June 15, 2026

Siemens Healthineers AG
Milind Dhamankar
Clinical Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Blvd.
Malvern, Pennsylvania 19355

Re: K253690
Trade/Device Name: LungMaps
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LNH
Dated: May 20, 2026
Received: May 20, 2026

Dear Milind Dhamankar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.06.15 15:50:18 -04'00'

Michael O'Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253690

Please provide the device trade name(s).

LungMaps

Please provide your Indications for Use below.

LungMaps is a post-processing software application for supporting the evaluation of lung perfusion and ventilation based on Magnetic Resonance Imaging (MRI). The software can be used for the creation of maps and statistical evaluations providing information on lung perfusion and ventilation.
Results when interpreted by a radiologist yield information that may assist in diagnosis. The results shall not be used as only source for diagnosis.
LungMaps is intended for patients aged 6 years and older who require evaluation of lung perfusion and/or ventilation.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92.

1. General Information

Establishment:

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared:

May 18, 2026

Manufacturer:

Siemens Healthineers AG
Magnetic Resonance (MR)
Allee am Röthelheimpark 2
91052 Erlangen
Germany
Registration Number: 3002808157

2. Contact Information

Milind Dhamankar
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Malvern, PA 19355, USA
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3. Device Name and Classification

Device/ Trade name:	LungMaps
Classification Name:	Automated Radiological Image Processing Software
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.2050
Classification:	II
Product Code:	Primary: QIH Secondary: LNH

4. Legally Marketed

Predicate Device[1]

Trade name:	syngo.MR Neuro fMRI – a part of syngo.MR Neurology
510(k) Number:	K182904
Classification Name:	Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.2050
Classification:	II
Product Code:	Primary: LLZ Secondary: LNH

Reference Device[1]**:**

Trade name:	Chondral Quant
510(k) Number:	K231351
Classification Name:	Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.2050
Classification:	II
Product Code:	Primary: LLZ Secondary: LNH

5. Indications for Use / Intended Use

LungMaps is a post-processing software application for supporting the evaluation of lung perfusion and ventilation based on Magnetic Resonance Imaging (MRI). The software can be used for the creation of maps and statistical evaluations providing information on lung perfusion and ventilation.

Results when interpreted by a radiologist yield information that may assist in diagnosis. The results shall not be used as only source for diagnosis.

LungMaps is intended for patients aged 6 years and older who require evaluation of lung perfusion and/or ventilation.

6. Device Description

The medical device LungMaps is a post-processing software application for supporting the evaluation of lung perfusion and ventilation based on Magnetic Resonance Imaging (MRI). The software can be used for the creation of maps and statistical evaluations providing information on lung perfusion and ventilation.

Version VA10A is the initial version of this medical device.

[1] The predicate and the reference device have not been subject to a design-related recall.

LungMaps processes one or multiple 2D time series of the lung MR images and provides perfusion-weighted and ventilation weighted maps of the lung.

The MR LungMaps application offers a range of possibilities to users, including series selection of input data, algorithm processing, data export of results, image, and result visualization, editing tools, and statistics calculation. This application is deployed as an OpenApp.

LungMaps consists of new and modified features that are similar to what is currently offered on the predicate device. The subject device includes the following modifications in comparison to the predicate device:

- New body region compared to predicate device
- Perfusion-weighted and ventilation weighted maps of the lung
- One or multiple 2D time series

7. Substantial Equivalence

LungMaps with software version VA10A is substantially equivalent to the following predicate and reference device:

Predicate Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
syngo.MR Neuro fMRI – a part of syngo.MR Neurology	K182904 - July 5, 2019.	LLZ, LNH	Siemens Healthcare GmbH
Reference Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
Chondral Quant	K231351– July 13, 2023	LLZ, LNH	Siemens Healthcare GmbH

8. Technological Characteristics

The subject device LungMaps with software version VA10A is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

The subject device conforms to the standard for medical device software (IEC 62304).

9. Nonclinical Tests

The following performance testing was conducted on the subject devices.

Performance Test	**Tested Software**	**Source/Rationale for test**
Solution Validation Report	LungMaps with software version VA10A	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
SW Sub-System Verification Test Reports		

An automatic lung segmentation algorithm based on deep learning is integrated into the LungMaps analysis. The architecture used for the segmentation task is based on the U-Net

architecture, which is the established state-of-the art method for medical image segmentation tasks.

To train the network, manual annotations were used that were all reviewed by a radiologist before being used for training, tuning, or testing. For training and testing, the Dice coefficient was selected to optimize the model. The Dice coefficient represents the primary evaluation end point. The Hausdorff distance, the average surface distance, and the volumetric difference are secondary evaluation metrics.

To train the algorithm, 1912 MR lung images were used. Training was performed on 193 subjects from 6 different data sources. Tuning was performed on 46 subjects and 382 images.

To test the algorithm, 342 images were used. On this test set, an average Dice score of 0.91 was achieved. The average and standard deviation (SD) for the Hausdorff distance is 4.1 (SD = 3.9) pixels and the average surface distance is 0.8 (SD = 0.8) pixels. The average absolute volumetric difference is 2.5 (SD = 159.5) and the relative volumetric difference is 3.2 (SD = 21.4).

The data set is a representative data set that included images acquired on 0.55T, 1.5T, and 3T MRI systems. The data set contains subjects with an age distribution from 6 to 85 years.

Any update on the network will only be implemented as a part of a new software version.

The datasets used for training were not used for validating or testing the algorithm.

Non-clinical tests such as unit test, integration testing, and system test are passed.

The system test results indicate that open defects were identified which had no impact on safety and effectiveness of LungMaps with software version VA10A.

10. Clinical Tests / Publications

No clinical tests were conducted for the subject device.

Clinical publications and other support documents were referenced to provide information on the use, testing and validation of the Subject Device. LungMaps produces results that are consistent with the implementation that has been evaluated in various scientific publications. The implementation in the scientific publications has been shown to correlate with standard of care techniques like DCE MRI, SPECT and 129Xe imaging and the same holds true for LungMaps.

No animal testing has been performed.

11. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971, to identify and provide mitigation of potential hazards early in the design cycle and continuously throughout the development of the product. Siemens Healthineers AG adheres to recognized and established industry standards, to minimize hazards. Furthermore, the device is intended for healthcare professionals.

LungMaps with software version VA10A conforms to the following standards:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
5-125	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Third Edition 2019-12	ISO
5-129	General I (QS/ RM)	Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1	62366-1:2015+AMD1:2020 (Consolidated Text)	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC

12. Conclusion as to Substantial Equivalence

The extensive testing of LungMaps with software version VA10A has been successfully completed. All risk mitigations, as identified in the Risk Analysis and all relevant requirements for LungMaps with software version VA10A have been tested and verified successfully.

Verification and validation of the product within the meaning of the Quality System Regulation (21 CFR § 820.30) have been performed by trained personnel. LungMaps with software version VA10A has been found to be validated for its intended use.

Indications for Use for subject device is different compared to the predicate device; however, it uses the same hosting platform syngo.via for both the subject device and the predicate device. Both the devices are integrated into the already cleared and marketed general *syngo*.via workflow concept. LungMaps processes perfusion-weighted and ventilation weighted maps of the lung, and predicate device *syngo*.MR Neuro fMRI processes fMRI statistical maps.

The difference between the predicate device and the subject device does not impact the safety and effectiveness of the subject device.

Therefore, it is Siemens' opinion that the safety and effectiveness of the subject device have been fully verified by objective evidence, and that the subject device performs as safely and effectively as the predicate device (K182904) and the subject device is substantially equivalent to the predicate device.