June 16, 2026

Siemens Healthcare GmbH
% Lynn Allman
Senior Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, California 94304

Re: K253264
Trade/Device Name: myAblation Guide (VC10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QTZ
Dated: May 18, 2026
Received: May 18, 2026

Dear Lynn Allman:

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,

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

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.	K253264

Please provide the device trade name(s).

myAblation Guide (VC10A)

Please provide your Indications for Use below.

MyAblation Guide is a software application for image processing, 2D/3D visualization, and comparison of medical images imported from multiple imaging modalities.

The software is controlled by the end user via a user interface on a workstation with DICOM connectivity or as an integrated version on a Siemens CT scanner workstation.

The application is used to assist in the preparation and performance of ablative procedures, including contouring of ablation targets, virtual ablation probe placement and contouring of ablated areas, as well as supporting the User in their assessment of the treatment.

The application can only be used by trained Users. The software is not intended for diagnosis and is not intended to predict ablation volumes or predict ablation success.

myAblation Guide is not intended for use in neurological or cardiac applications and is not intended for pediatric patients (pediatric patients according to US Law 21 CFR 814.3(s)).

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

myAblation Guide (Version VC10A)

The following information is provided as required by 21 CFR 807.92

I. Submitter, Manufacturer, and Importer/Distributor Information:

Name and Address:	Varian Medical Systems Inc. 3100 Hansen Way, Palo Alto CA 94304
Contact Name:	Lynn Allman, Senior Director Regulatory Affairs
E-mail:	submissions.support@varian.com
Phone Number:	(650) 424-5369
Date Prepared:	September 17, 2025
Manufacturer Name:	Siemens Healthcare GmbH
Mfg. Address:	Henkestr. 127 91052 Erlangen Germany
Importer/Distributor Name and Address:	Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard Malvern, PA 19355
Importer/Distributor Establishment Registration Number:	2240869

II. Device Information:

Proprietary Name:	myAblation Guide (VC10A)
Common/ Usual Name:	System, Image Processing, Radiological
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
Regulation Number:	§892.2050 Medical image management and processing system
Product Code	QTZ

III. Predicate Device:

myAblation Guide (K240796)

This predicate has not been subject to a design-related recall.

IV. Subject Device Description:

myAblation Guide is a software medical device that is used in the context of percutaneous ablative procedures with straight instruments. It is used by clinical professionals in a hospital premise; it can be either deployed on compatible CT scanners or a computer workstation.

The application is operated by medical professionals such as Interventional Radiologists and medical technologists with current license and/or certification as required by regional authority. myAblation Guide allows operating functions in an arbitrary sequence. In addition, it includes a structured sequence of steps for ease of utility.

The application supports anatomical datasets from CT, MR, CBCT, as well as PET/CT.

The application includes means and functionalities to support in:
• Multimodality viewing and contouring of anatomical, functional, and multi-parametric images such as CT, CBCT, PET/CT, MRI
• Multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP), volume rendering technique (VRT)
• Freehand and semi-automatic contouring of regions-of-interest on any orientation including oblique
• Algorithmically supported contouring of targets and ablated tissue in the liver, kidney and lung (target only) on contrast-enhanced CT images
• Manual and semi-automatic registration using rigid and deformable registration
• Expansion of created contour structures to visualize a safety margin
• Functionality to support the user in creating virtual ablation needle paths and associated virtual ablation zones derived from manufacturer data
• Export of virtual needle paths in the Dicom SSO format
• Supports the user in comparing, contouring, and ablation needle planning based on datasets acquired with different imaging modalities
• Supports multimodality image fusion
• Supports user's procedure flow via a task stepper

Thermal ablation cannot be triggered from myAblation Guide.

V. Intended Use Statement/Indications for Use Statement:

MyAblation Guide is a software application for image processing, 2D/3D visualization, and comparison of medical images imported from multiple imaging modalities.

The software is controlled by the end user via a user interface on a workstation with DICOM connectivity or as an integrated version on a Siemens CT scanner workstation.

The application is used to assist in the preparation and performance of ablative procedures, including contouring of ablation targets, virtual ablation probe placement and contouring of ablated areas, as well as supporting the User in their assessment of the treatment. The application can only be used by trained Users.

The software is not intended for diagnosis and is not intended to predict ablation volumes or predict ablation success.

Contraindications:
myAblation Guide is not intended for use in neurological or cardiac applications and is not intended for pediatric patients (pediatric patients according to US Law 21 CFR 814.3(s)).

VI. Substantial Equivalence Discussion:

The following table compares the subject device to the predicate device with respect to indications for use, principles of operation, technological characteristics, and performance, and forms the basis for the determination of substantial equivalence.

Table 1: Comparison of Technological Characteristics between subject and predicate devices

Feature And/or Specification Of New/Modified Device	**Predicate Device 510(K) ID #K240796 myAblation Guide (VB80A)**	**Subject Device myAblation Guide (VC10A)**	**Analysis/Differences**
Intended Use / Indications for Use	MyAblation Guide is a software application for image processing, 2D/3D visualization, and comparison of medical images imported from multiple imaging modalities. The software is controlled by the end user via a user interface on a workstation with DICOM connectivity or as an integrated version on a Siemens CT scanner workstation. The application is used to assist in the preparation and performance of ablative procedures, including contouring of ablation targets, virtual ablation probe placement and contouring of ablated areas, as well as supporting the User in their assessment of the treatment. The application can only be used by trained Users. The software is not intended for diagnosis and is not intended to predict ablation volumes or predict ablation success.	MyAblation Guide is a software application for image processing, 2D/3D visualization, and comparison of medical images imported from multiple imaging modalities. The software is controlled by the end user via a user interface on a workstation with DICOM connectivity or as an integrated version on a Siemens CT scanner workstation. The application is used to assist in the preparation and performance of ablative procedures, including contouring of ablation targets, virtual ablation probe placement and contouring of ablated areas, as well as supporting the User in their assessment of the treatment. The application can only be used by trained Users. The software is not intended for diagnosis and is not intended to predict ablation volumes or predict ablation success.	Same as predicate
Intended Users	Physicians	Physicians	Same as predicate
Intended patient population	The patient demographic chosen by interventional radiologists to undergo ablation treatment	The patient demographic chosen by physicians to undergo percutaneous ablation treatment	Same as predicate

	(including patient with soft tissue lesions).	(including patient with soft tissue lesions).	
US product code	QTZ (21 CFR 892.2050)	QTZ (21 CFR 892.2050)	Same as predicate
Operating Environment	Operating Room and the hospital healthcare environment	The application can be used on a standalone workstation, a server-client solution and on CT systems manufactured by Siemens Healthineers with software level Somaris 10 or higher. These items are generally located within a hospital, radiology center, or out-patient clinic environment. If application is used during an interventional procedure, in addition to planning, the application resides in the control room of the imaging modality.	Same as predicate – details were added here to give further clarity on where the application may be accessed from in the healthcare setting.
Operating System / Platform	Microsoft Windows 10, syngo.via VB80, syngo.via View&Go VA50A & VA55A, syngo.CT VB10	Microsoft Windows 10, syngo.via VC10A, syngo.via View&Go VA60A, syngo.CT VB20A	Substantially equivalent Verification and validation of software updates to maintain support for the listed operating platforms do not raise significantly different concerns about safety or effectiveness.
Supported modalities	CT, MRI, CBCT, as well as PET/CT	CT, MRI, CBCT, as well as PET/CT	Same as predicate
(Semi-)Automatic Structure Segmentation	Yes, for liver	Yes, for liver, lung and kidney	Substantially equivalent – this is a modification to add to the existing library of segmentation algorithms. Verification and validation of these structure segmentation algorithms do not raise significantly different concerns of safety or effectiveness.
Target Structure Margin Indication	Yes	Yes	Same as predicate
Simulation of Virtual Needle Path (Virtual Ablation Probe Planning)	Yes	Yes	Same as predicate
3D Visualization of segmented structures, including Ablated Area	Yes	Yes	Same as predicate
Data export to SHS myNeedle Guide on Siemens Healthineers syngo CT systems	Yes	Yes	Same as predicate
Image registration: Overlay of Virtual Ablation Probe and Achieved Ablation Probe Position	Yes	Yes	Same as predicate
Image registration: Overlay of planned and achieved ablation	Yes	Yes	Same as predicate

zone in 2D/3D for visual Evaluation of Ablation Result			
(Semi-)Automatic Segmentation of Ablated Areas	Yes, for liver	Yes, for liver and kidney	Substantially equivalent – this is a modification to add to the existing library of segmentation algorithms. Verification and validation of these segmentation algorithms do not raise significantly different concerns of safety or effectiveness.
Quantitative Evaluation of Ablation Result	No	No	Same as predicate
Qualitative representation of target structure and margin to ablation zone	No	Yes	Substantially equivalent – this is a new feature in the subject device version. Verification and validation of these algorithms do not raise significantly different concerns of safety or effectiveness.
Visualization of organs-at-risk	No	No	Same as predicate

VII. Performance Data:

1. Non-clinical Testing:

myAblation Guide underwent non-clinical testing to demonstrate the design and performance of the devices meet the established design criteria and are substantial equivalent to the predicate devices. The subject device successfully completed functional, usability, and other software-related design testing.

Semi-automatic segmentation algorithms:

Lung lesion segmentation:

A retrospective internal study was conducted to evaluate the semi-automatic lung lesion segmentation algorithm, including 81 patients with solid lung lesions and 78 patients with subsolid lung lesions. Ground truth data was created by a board-certified radiation oncologist by performing manual sliceby-slice delineation of lesion volumes.

The semi-automatic lung module segmentation algorithm integrated into myAblation Guide software is a non-AI algorithm based on a region growing implementation that segments lesions based on seed points and iterative adding of neighboring image pixels, of which intensity values are sufficiently similar to the region, until no more neighbors meet the criterion. Depending on the lesion type, the user can select the type of lung lesion to be segmented (solid and subsolid).

The performance of the semi-automatic lung lesion segmentation algorithm has been evaluated in an internal test. This internal analysis included a total of 81 patients with a total of 83 solid lesions and 78 patients with 80 subsolid lesions.

Metric	**Solid lesion**	**Subsolid lesion**
Dice / True Positive Lesion	0.74	0.7
Sensitivity	0.98	0.95

For solid lesion types comprising 83 lesions, the Dice is 0.74 with a sensitivity of 0.98. For subsolid lesion types comprising 80 lesions, the Dice is 0.7 with a sensitivity of 0.95.

Renal lesion segmentation:

The clinical performance testing of the semi-automatic renal lesion and renal ablation zone segmentation has been evaluated in a retrospective internal study. A total of 45 patients have been assessed. The evaluated cases comprise renal lesions and ablation zones.

This algorithm is based on a random walker implementation that assigns image labels by calculating probabilities that a random walk from each pixel reaches a predefined seed region.

The performance of this algorithm has been tested in an internal test. This internal analysis of the renal lesion segmentation included a total of 45 patients with 45 lesions and 18 ablation zones. We used two metrics to quantify the segmentation quality. The first metric, the DICE

coefficient, is used as a measure for evaluating segmentation quality. It quantifies the spatial overlap between the predicted segmentation and the reference ground truth, with higher values indicating better agreement.

Sensitivity is referred to as: "Sensitivity = TP / (TP + FN)" with true positive (TP) defined as Intersection over Union (IoU) ≥ 0.1 and false negative (FN) as IoU < 0.1. Correspondingly, a sensitivity of 0.97 means that, statistically, 97 out of 100 lesion have been segmented and fulfil the requirement of IoU < 0.1.

The DICE for all renal lesion types is 0.62 with a sensitivity of 0.97, as outlined in the following table:

Metric	**All Lesion Types**
Dice / True Positive Lesion	0.62
Sensitivity	0.97

The ablation zone algorithm analysis involved a total of 45 patients with 18 available ablation zones. The DICE for renal ablation zones is 0.58 and the overall sensitivity with 0.92, as outlined the following table:

Metric	**Ablation Zone**
Dice / True Positive Renal Ablation Zone	0.58
Sensitivity	0.92

2. Clinical Testing (N/A):

No clinical studies were carried out for the subject device, and therefore, no such clinical data is provided within this submission.

3. Software, Cybersecurity, and Interoperability

Software verification was conducted in accordance with IEC 62304 – "Medical device software - Software life cycle processes" and FDA guidance "Content of Premarket Submissions for Device Software Functions.

Cybersecurity and Interoperability requirements were assessed per FDA guidance's Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Postmarket Management of Cybersecurity in Medical Devices, Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices".

Cybersecurity considerations related to the subject device are included within this submission. Siemens Healthineers conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

VIII. Conclusion:

Performance tests were conducted to test the functionality of the device. These tests have been performed to assess the functionality of the subject device. Results of all testing conducted were found acceptable in support to determine similarities to the predicate /previously cleared device.

Device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management was implemented throughout the development process to control potential hazards.

The device does not come in contact with the patient and is only used by trained professionals. The output of the device is evaluated by clinicians, providing for sufficient review to identify and intervene in the event of a malfunction. The manufacturer believes that the subject device is safe and effective as the identified predicate device and does not introduce new safety and effectiveness concerns.

Assessment on Substantial Equivalence:

The comparison of intended use, technological characteristics, performance specifications, device hazards as well as verification and validation results demonstrate that myAblation Guide is as safe, as effective, and performs as well as the predicate device. In summary, the manufacturer is of the opinion that myAblation Guide does not introduce any new significant potential safety risks and is similar to the predicate device.