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

August 6, 2024

Re: K240796
Trade/Device Name: myAblation Guide (VB80A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QTZ
Dated: July 15, 2024
Received: July 16, 2024

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 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, 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)*
K240796

Device Name
myAblation Guide (VB80A)

Indications for Use *(Describe)*
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.

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.

510(k) Summary

myAblation Guide (Version VB80A)

The following information is provided as required by 21 CFR 807.92

I. Submitter and Manufacturer 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
Date Prepared:	August 6th, 2024
Manufacturer Name:	Siemens Healthcare GmbH
Mfg. Address:	Henkestr. 127 91052 Erlangen Germany

II. Device Information:

Proprietary Name:	myAblation Guide (VB80A)
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:

Aline Ablation Intelligence 1.0.0 (K202297)

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
• 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. 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.

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.

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

Feature And/or Specification Of New/Modified Device	Predicate Device 510(K) ID # K202297 Aline Ablation Intelligence (From Mirada Medical)	MyAblation Guide (Subject Device)	Analysis/Differences
Indications for Use	Aline Ablation Intelligence is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures. Aline Ablation Intelligence is controlled by the user via a user interface on a workstation. Aline Ablation Intelligence imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures. Aline Ablation Intelligence is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. Aline Ablation Intelligence is used to assist physicians in confirming ablation zones. The software is not intended for diagnosis. The software 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.	Substantially equivalent The myAblation Guide intended use is similar to the intended use of the predicate device. Both devices are used to process a variety of medical images in support of ablation procedures.
Intended Users	Physicians	Physicians	Same as predicate
Intended patient population	The patient demographic chosen by interventional radiologists to undergo ablation treatment (including patient with soft tissue lesions).	The patient demographic chosen by physicians to undergo percutaneous ablation treatment (including patient with soft tissue lesions).	Same as predicate
US product code	21 CFR 892.2050	21 CFR 892.2050	Same as predicate
Operating Environment	Operating Room and the hospital healthcare environment such as interventional radiology control room.	Operating Room and the hospital healthcare environment	Same as predicate

Feature And/or Specification Of New/Modified Device	Predicate Device 510(K) ID # K202297 Aline Ablation Intelligence (From Mirada Medical)	MyAblation Guide (Subject Device)	Analysis/Differences
Operating System / Platform	Microsoft Windows compatible machine. 64-bit Windows 7 and 10.	Windows 10	Substantially equivalent
Supported modalities	CT, MRI.	CT, MRI, PET, PET-CT, CBCT images	Substantially equivalent Software validation and verification tests to ensure the performance and compatibility of modalities not seen in the predicate do not raise different concerns of safety or effectiveness.
(Semi-)Automatic Structure Segmentation	Yes	Yes, for livers	Substantially equivalent
Structure Margin Indication	Yes	Yes	Substantially equivalent
Simulation of virtual needle path (Virtual Ablation Probe Planning)	Yes	Yes	Substantially equivalent
3D Visualization of segmented structures, including Ablation Zone	Yes	Yes	Substantially equivalent
Data export to myNeedle Guide on Siemens Healthineers syngo CT systems	No	Yes	Substantially equivalent Data export tests to these compatible devices do not raise significantly different concerns of safety or effectiveness.
Image registration: Overlay of Virtual Ablation Probe and Achieved Ablation Probe Position	Yes	Yes	Substantially equivalent
Image registration: Overlay of planned and achieved ablation zone in 2D/3D for visual Evaluation of Ablation Result	Yes	Yes	Substantially equivalent

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:

The clinical performance testing of the semi-automatic liver lesion and liver ablation zone segmentation has been evaluated by Moltz et al (Moltz J. &.-O., 2008) as well as in a retrospective internal study. Altogether, CT-datasets from 60 patients have been assessed. The evaluated cases comprise hepatocellular carcinoma (HCC) and non-HCC cases.

To assess the algorithm's performance on liver metastases, Moltz et al conducted a study evaluating five different data sets comprising of ten liver metastases originating from diverse primary tumors. With a Dice coefficient (Dice similarity index) of 0.82 the algorithm effectively demonstrated the segmentation of both hyperdense and hypodense lesions, regardless of their placement within the liver or in its surrounding areas.

(The tabulated results were converted for the purpose of comparing them with our internal study.)
The internal analysis of the lesion segmentation included a total of 50 patients. The DICE for all lesion types is 0.65 with a sensitivity of 0.82, as outlined in the following table:

Metric	All Lesion Types	HCC	non-HCC
Dice / True Positive Lesion	0.65	0.62	0.66
Sensitivity	0.82	0.81	0.81

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 0.82 means that statistically, 82 out of 100 lesions have been segmented and fulfil the requirement with IoU ≤ 0.1. The ablation zone algorithm analysis involved a total of 33 patients with 41 available ablation zones. The DICE for liver ablation zones is 0.65 with an overall sensitivity of 0.95.

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 substantially equivalent to the predicate device. In summary, the manufacturer is of the opinion that myAblation Guide does not introduce any new potential safety risks and is similar to the predicate device.