December 16, 2025

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

Re: K252919
Trade/Device Name: Identify (5.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: September 12, 2025
Received: September 12, 2025

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.

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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.	K252919

Please provide the device trade name(s).

IDENTIFY (5.0)

Please provide your Indications for Use below.

IDENTIFY is indicated for adult patients undergoing radiotherapy treatment simulation and/or delivery. IDENTIFY is indicated for positioning of patients, and for monitoring patient motion including respiratory patterns. It allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.

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

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

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A Siemens Healthineers Company

510(k) Summary K252919

IDENTIFY 5.0

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Lynn Allman, PhD., Senior Director Regulatory Affairs
Phone : (650) 424-5369
E-mail : submissions.support@varian.com
Date Prepared: 12 September 2025

II. Device Information

Proprietary Name: IDENTIFY (5.0)
Regulation Number: 21 CFR §892.5050
Classification Name: Accelerator, linear, medical
Product Code: IYE
Common Name: Patient identification & positioning/tracking system

III. Predicate Device

Proprietary Name: IDENTIFY 4.0 (K242957)
Regulation Number: 21 CFR §892.5050
Classification Name: Accelerator, linear, medical
Product Code: IYE
Common Name: Patient identification & positioning/tracking system

IV. Device Description

IDENTIFY uses surface guidance technology to monitor patient motion during radiotherapy treatment simulation and delivery. Its high precision SGRT cameras support:

- Positioning of the patient for treatment delivery
- Monitoring of the patient position during treatment delivery
- Respiratory motion management during simulation and treatment delivery

Figure 01 depicts the IDENTIFY 5.0 system.

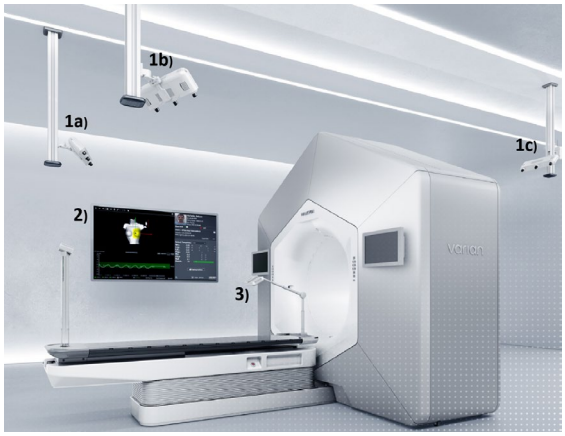

Figure 01: Treatment room variant of IDENTIFY (5.0), depicting subsystem components:
1 a-c) Surface guidance cameras 2) Wall mount display 3) Visual coaching device

V. Intended Use

IDENTIFY is intended for patient motion monitoring, including monitoring of respiratory patterns. It can be used during radiotherapy treatment simulation and delivery and allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.

VI. Indications for Use

IDENTIFY is indicated for adult patients undergoing radiotherapy treatment simulation and/or delivery. IDENTIFY is indicated for positioning of patients, and for monitoring patient motion including respiratory patterns. It allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1 Comparison of Subject Device to Predicate Device

Feature and/or Specification of new/modified device	Predicate Device 510(k) # K242957 IDENTIFY 4.0	Subject device IDENTIFY 5.0	Comparison
Indications for Use	IDENTIFY is indicated for adult patients undergoing radiotherapy treatment simulation and/or delivery. IDENTIFY is indicated for positioning of patients, and for monitoring patient motion including respiratory patterns. It allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.	IDENTIFY is indicated for adult patients undergoing radiotherapy treatment simulation and/or delivery. IDENTIFY is indicated for positioning of patients, and for monitoring patient motion including respiratory patterns. It allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.	No change.
Intended Use	IDENTIFY is intended for patient motion monitoring, including monitoring of respiratory patterns. It can be used during radiotherapy treatment simulation and delivery and allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.	IDENTIFY is intended for patient motion monitoring, including monitoring of respiratory patterns. It can be used during radiotherapy treatment simulation and delivery and allows for data output to radiotherapy devices to synchronize image acquisition or treatment delivery with the acquired motion information.	No change.
Patient motion monitoring			
Auto capture of the reference surface at the start of CBCT imaging (for ADI+ connected Varian linacs)	No	**Yes**	**Changed, substantially similar. Enables IDENTIFY to capture a reference surface that represents max inhale, max exhale or mid ventilation of the respiratory cycle.**
Automated MV beam-hold (for ADI+ connected Varian linacs)	No	**Yes**	**Changed, substantially similar. Enables additional delivery systems (Ethos Radiotherapy**

Feature and/or Specification of new/modified device	Predicate Device 510(k) # K242957 IDENTIFY 4.0	Subject device IDENTIFY 5.0	Comparison
			System, Halcyon) to synchronize MV beam delivery with motion information from IDENTIFY
Send couch shifts to the treatment console (for ADI+ connected Varian linacs)	No	Yes	Changed, substantially similar. Enables the delivery systems (Ethos Radiotherapy System, Halcyon) to receive information for couch position adjustments
Auto alignment of the reference surface with couch movements (for ADI+ connected Varian linacs)	No	Yes	Changed, substantially similar. Enables IDENTIFY to adjust the reference surface based on couch position information received by the delivery systems (Ethos Radiotherapy System, Halcyon)
Automated kV beam-hold during imaging (for ADI+ connected Varian linacs)	No	Yes	Changed, substantially similar. Enables the delivery systems device to pause kV beam delivery if the motion observed by IDENTIFY exceeds defined thresholds.
Compatibility			
Varian Halcyon, Ethos Radiotherapy System interfaced 5.0 (Concurrent 510(k) submission)	Standalone	Interfaced and Standalone	Changed, substantially similar.

Note:
ADI+: Auxiliary Device Interface+

VIII. Summary of Performance Testing (Non-Clinical Testing)

The following performance data was provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC)

IDENTIFY has undergone EMC Testing. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Product verification and Validation testing

IDENTIFY has undergone formal hardware and software verification and validation testing including usability testing; and it demonstrates the device performs as intended.
Testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, and ISO 14971 Risk Management Standard and the other FDA recognized consensus standards listed in Table 2.
Performance testing evaluated the accuracy of patient positioning, motion monitoring, and respiratory pattern detection under simulated clinical conditions. The system passed positioning accuracy and motion detection to its specifications, and successful synchronization in all test scenarios.
Usability testing was performed with representative clinical users (radiation therapists) to evaluate the ease of use, clarity of instructions, and workflow integration. All users completed the required tasks successfully. No critical errors were observed.

Software Verification and Validation Testing

IDENTIFY has undergone software verification and validation testing and documentation has been provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."
Comprehensive software testing was performed, including unit, integration, and system-level tests, as well as risk-based testing for safety-critical functions. All software functions operated as intended.
The documentation level required for IDENTIFY 5.0 is "Enhanced", as a failure or flaw of the software function(s) could present a hazardous situation with probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use, as noted in the Level of Concern. The software for this device is considered as a "Major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Use of Consensus Standards:

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

Table 2 List of Consensus Standards

Standard			
ISO 14971:2019	ISO 15223-1:2021	IEC 80001-2-2: 2012	IEC 60601-1:2005/AMD2:2020
IEC 61217:2011	IEC 62366-1:2015 +A1:2020	IEC 80001-1:2021	IEC 60601-1-2:2014 +A1 2021
ISO 20417:2021	IEC 62304:2006+A1:2015	IEC 81001-5-1:2021	IEC 60601-1-6:2010/AMD2:2020

IX. Summary of non-applicable Testing

Clinical Testing
No animal or clinical studies were conducted.

Magnetic Resonance Testing (MR)
No MR claims are being made; thus, the MR Safety status of IDENTIFY has not been evaluated.

Biocompatibility Testing
There are no tissue contacting components in IDENTIFY, therefore biocompatibility evaluation does not apply to this device.

Cleaning, Disinfection, Sterilization, Reprocessing
IDENTIFY is supplied nonsterile.

X. Determination of Substantial Equivalence to the Predicate Device

The intended use and indications for use are the same as the predicate device. There is no change to the principle operation of the device. Varian believes the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness. The results of verification and validation as well as conformance to relevant safety standards demonstrate that the device meets the safety and performance criteria. Varian considers IDENTIFY 5.0 to be as safe and effective as the predicate and to perform at least as well as the predicate device (K242957).