



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

February 7, 2025

Re: K242957

Trade/Device Name: Identify (4.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: January 7, 2025
Received: January 8, 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,

Digitally signed by Michael D.

O'hara -S

Date: 2025.02.07 16:52:37 -05'00' For

Lora Weidner

Assistant 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

Submission Number (if known)

K242957

Device Name

IDENTIFY (4.0)

Indications for Use (Describe)

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.

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.

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PREMARKET NOTIFICATION

510(k) Summary

IDENTIFY

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way Palo Alto CA94304 Dr. Lynn Allman-Senior Director Regulatory Affairs Phone: (650)-424-5369 E-mail: submissions.support@varian.com Date: 24 September 2024
Proprietary Name:	IDENTIFY
Classification Name:	accelerator, linear, medical 21CFR892.5050, IYE, Class II
Common/Usual Name:	Patient identification & positioning/tracking system
Predicate Device:	IDENTIFY (K230576)
Device Description:	IDENTIFY is a system for motion monitoring during radiotherapy treatment simulation and delivery. It incorporates patient safety, quality, and workflow efficiency. Its high precision SGRT cameras support proper patient positioning and enable to monitor the patient's respiratory motion and to detect intra-fraction patient position changes during the treatment.
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.
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.
Significant differences:	• TrueBeam Couch Control for couch position correction • Optional handheld free workflow • SRS mode to switch from cm to mm display scale • Planning Tool accessibility on ARIA workstation

Non-clinical Testing

Hardware and software verification and validation testing was conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards listed below. Test results showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was 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. The documentation level required for IDENTIFY v4.0 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.

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on this medical device. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Standards Conformance

IDENTIFY conforms to the following FDA recognised standards:

ISO 14971:2019
ISO 15223-1:2021
ISO 20417:2021
IEC 60601-1:2005/AMD2:2020
IEC 60601-1-2:2014 +A1 2021 (4th Edition)
IEC 60601-1-6:2010/AMD2:2020
IEC 62366-1:2015 +A1:2020
IEC 62304:2006+A1:2015
IEC 61217:2011
IEC 80001-1:2021
IEC 80001-2-2: 2012
IEC 81001-5-1:2021

IDENTIFY also complies with the following non-FDA recognised standards:

ISO 13485:2016

Conclusion of Non-Clinical testing

The outcome was that the product conformed to the defined user needs and intended uses and that there were no DRs (discrepancy reports/Unresolved Anomalies) remaining which had a priority of Safety Intolerable or Customer Intolerable (applicable to the US). Varian therefore considers Identify to be safe and effective and to perform at least as well as the predicate device.

Argument for Substantial Equivalence to the Predicate Device

A subset of technological characteristics of the current device is different to the predicate. These differences are all considered by Varian to be enhancements of the predicate. There are no changes in the principle of operation of the device. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes that Identify is substantially equivalent to the predicate.