January 21, 2026

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

Re: K252977
Trade/Device Name: Halcyon, Ethos Radiotherapy System (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 15, 2025
Received: September 17, 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.	K252977

Please provide the device trade name(s).

Halcyon, Ethos Radiotherapy System (5.0)

Please provide your Indications for Use below.

Halcyon and Ethos radiotherapy system are indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation is indicated for adults and pediatric patients.
Halcyon and Ethos radiotherapy system with the HyperSight imaging feature produce kV CBCT anatomical images that can be used in the simulation and planning of radiation therapy.

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)

K252977

varian
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PREMARKET NOTIFICATION

510(k) Summary

K252977

Halcyon and Ethos Radiotherapy

System As required by 21 CFR 807.92

Submitter's Name:

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto CA94304

Contact Name: Lynn Allman-Senior Director Regulatory Affairs
Phone: 650/424.5369
E-mail: submissions.support@varian.com
Date: 20 January 2026

Proprietary Name:

Halcyon, Ethos Radiotherapy System (5.0)

Classification Name:

Medical charged-particle radiation therapy system
21CFR892.5050, IYE, Class II

Common/Usual Name:

Medical Linear Accelerator

Predicate Devices:

Halcyon, Ethos Radiotherapy System (K232113).

Device Description:

Halcyon and Ethos Radiotherapy System are single energy medical linear accelerators (linacs) designed to deliver Image Guided Radiation Therapy and radiosurgery, using Intensity Modulated and Volumetric Modulated Arc Therapy techniques. They consist of the accelerator and patient support within a radiation shielded treatment room and a control console outside the treatment room.

An electron gun generates electrons which are accelerated by radio frequency (RF) power from a magnetron. The electrons strike a tungsten target producing photons (X-rays) for treatment and MV Imaging. The photons produced by the target are monitored and controlled by a pressurized ion chamber.

A beam collimation subsystem consisting of a primary and secondary collimator and two stacked multileaf collimators (MLCs) shapes the photon beam to define the treatment area.

X-Ray images of the patient are used by the treater to verify the correct treatment location. MV Imaging uses the treatment beam and a flat panel imager whereas kV imaging uses a high-capacity kV X-ray tube, a kV collimation system with full fan bowtie filter with movable y-blades to define the imaging beam size and to capture the image, a kV imager.

	Halcyon and Ethos radiotherapy system deliver a treatment generated by a Treatment Planning System from a physician's prescription. kV CBCT images from the HyperSight imaging system can additionally be used for planning treatments. Ethos radiotherapy system is capable of delivering adaptive treatments which can take into account changes in tumour geometry between treatment sessions.
Intended Use	Halcyon and Ethos Radiotherapy System are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated. The intended use is the same as the predicate.
Indications for Use:	Halcyon and Ethos radiotherapy system are indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation is indicated for adults and pediatric patients. Halcyon and Ethos radiotherapy system with the HyperSight imaging feature produce kV CBCT anatomical images that can be used in the simulation and planning of radiation therapy. The Indications for Use has minor rewording for clarity and is compared with the predicate version in the Non-Significant Changes section of this document.

Significant differences:

The significant differences compared to the predicate are:

<u>PerfectKinetix dynamic couch</u>
The new PerfectKinetix dynamic couch permits the translational movements available in the 3 DoF Couch, but adds 3 rotational directions: pitch, roll, and yaw to make a total of 6 Degrees of Freedom (6 DoF). The rotational movements allow for an additional 3 DoF in which to correct the patient position.
The new couch is intended to enable users to streamline the patient positioning processes by including rotational movements (i.e. pitch, yaw, and roll) in the patient alignment steps. Note that it does not support planned rotations. The rotations are only available to correct the position of the patient to match the initial treatment plan.

<u>Beam Hold Interface-Manually Added Gating Flag.</u>
HAL 5.0 provides an interface to allow the treater to add beam hold information manually when using versions of Aria Treatment Management before v18 and the current version of Ethos Treatment Management Planning Software in which a gating flag is not supported.
When a beam hold device is configured and enabled, HAL prompts the treater to confirm its use, and once authenticated, the setting is saved for treatment delivery. (Referred to as Manual Gating Flag in some documents).

<u>Customer HASP</u>
HAL 5.0 introduces the Customer HASP user group, enabling hospital-employed individuals trained by Varian to perform basic preventive and corrective maintenance tasks on radiation therapy products, similar to Varian Service Representatives, provided they complete the HAL Technical Maintenance Training and hold a service agreement.

However, this user group has limited system access—it cannot modify read-only or hidden parameters in Machine Performance Check, edit Peer Sync profiles or wox files, nor access the new Treatment Application Advanced Diagnostic feature.

Non-Significant Changes

New features
Easier 3rd Party Licensing.
Energy Star Ready.

Modified Features
Beam Hold for All kV Configurations.
7195 Magnetron Ready
M110 Modulator
Adjustable PRF (Pulse Rate Frequencies) to Mitigate Guide Rejection
IDENTIFY Workflow Improvements
IEC Recording for Beam Hold
Cybersecurity Improvements
Dual DICOM for 3P
Improvements to HyperSight Imaging
Advanced Diagnostics
Clarification of HU Requirements for HyperSight Imager Across CBCTp and IGRT Workflows
Configuration with Standard Imager for Ethos

The minor change to the indications for Use is in italics in the new version below.

Indications for Use (Predicate)
Halcyon and Ethos radiotherapy system are indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated for adults and pediatric patients.
The Halcyon and Ethos Radiotherapy System produce CBCT images that can be used in Image Guided Radiation Therapy, and the simulation and planning for radiation therapy.

Indications for Use (HAL 5.0)
Halcyon and Ethos radiotherapy system are indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation is indicated for adults and pediatric patients. Halcyon and Ethos *radiotherapy system with the HyperSight imaging feature produce kV CBCT anatomical images that can be used in the simulation and planning of radiation therapy*.

Non-clinical Testing

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

Electrical Safety and Electromagnetic Compatibility (EMC)

HAL5.0 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

HAL 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 the Standards conformance section of this document.

Performance testing of HAL 5.0 evaluated the accuracy of patient positioning, treatment-workflow behavior, and system responsiveness associated with its three significant new capabilities: the PerfectKinetix Dynamic Couch, the Beam Hold Interface with manually added gating flag, and Customer HASP functionality.

For the **PerfectKinetix Dynamic Couch**, testing assessed translational and rotational corrections under simulated clinical conditions, confirming precise 6-Degree-of-Freedom alignment and stable motion control across all corrective directions.

The **Beam Hold Interface–Manually Added Gating Flag** was tested by simulating gating-dependent delivery workflows using ARIA with Halcyon and Ethos configurations that do not natively support gating; results demonstrated reliable user prompting, correct interlock behavior, and consistent treatment-beam suspension and resumption without missed or unintended beam transitions.

Evaluation of the **Customer HASP** feature verified that restricted-access service actions could be performed safely by trained customer personnel while maintaining all system protections, including lockouts on non-permitted functions and preservation of essential performance. Across all scenarios, HAL 5.0 met its performance specifications, with patient-positioning accuracy, workflow execution, and safety-critical behaviors consistently achieving expected results and demonstrating full functional readiness.

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

HAL 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 HAL 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.

Standards Conformance

Halcyon and Ethos Radiotherapy System conform to the following FDA recognised standards

Standards Organization	Standard / Number and Date	Standard Name	FDA Recognition Number
ANSI AAMI ISO	14971:2019	Medical devices – Application of risk management to medical devices	5-125
ISO	15223-1 Fourth edition 2021-07	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	5-134
ANSI AAMI ISO	10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	2-258
ANSI AAMI IEC	62304:2006/A1:2016	Medical device software – Software life cycle processes [Including Amendment 1 (2016)]	13-79
ANSI AAMI IEC	62366-1:2015+AMD1:2020 (Consolidated Text)	Medical devices – Part 1: Application of usability engineering to medical devices including Amendment	5-129
ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1)	19-46
IEC	60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	19-49
IEC	60601-2-1 Edition 4.0 2020-10	Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of gantry-based radiation therapy systems	12-338
iEC	60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]	19-36
IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment – Part 1-6: General requirements – Collateral Standard: Usability	5-132
IEC	60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment – Part 1-3: General requirements for radiation protection in diagnostic X-ray equipment	Not specified

IEC	60601-2-68 Edition 1.0 2014-09	Medical electrical equipment – Part 2-68: Particular requirements for X-ray-based image-guided radiotherapy equipment	12-319
IEC	60601-2-44 Edition 3.2:2016	Medical electrical equipment – Part 2–44: Particular requirements for X-ray equipment for computed tomography	12-302
IEC	60976 Edition 2.0 2007-10	Medical electron accelerators – Functional performance characteristics	12-253
IEC	61217 Edition 2.0 2011-12	Radiotherapy equipment – Coordinates, movements, and scales	12-267
IEC	62274 First Edition 2005-05	Safety of radiotherapy record and verify systems	12-241
AAMI	RT2:2017	Radiation therapy readiness check	12-307
IEC	60976 Edition 2.0 2007-10	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	12-253
IEC	60825-1:2014	Safety of laser products –Part 1: Equipment classification and requirements	12-273

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) remaining which had a priority of Safety Intolerable or Customer Intolerable. Varian therefore considers Halcyon and Ethos radiotherapy System 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 and features of the current device is different to the predicate. These differences are all considered by Varian to be enhancements of the predicate. The Intended Use is unchanged and indications for use has minor rewording for clarity. 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.

Referring to the 510(k) Decision-Making Flowchart in "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" Guidance Notes:

1. The predicate (Halcyon and Ethos Radiotherapy System 4.0) is a legally marketed device. (K232113).
2. The device and its predicate have the same intended use.

Varian therefore believes that Halcyon and Ethos Radiotherapy System are substantially equivalent to the predicate.