August 3, 2026

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

Re: K261856
Trade/Device Name: Halcyon, Ethos Radiotherapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 3, 2026
Received: June 4, 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,

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

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)*
K261856

Device Name
Halcyon, Ethos Radiotherapy System

Indications for Use *(Describe)*
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 Halcyon and Ethos Radiotherapy systems may be used in the delivery of radiation treatment for adults with the following non-cancerous medically refractory hyperproliferative disorders: Dupuytren's contracture, Ledderhose disease, heterotopic ossification, and keloids; and low dose radiotherapy for adults with non-cancerous medically refractory osteoarthritis; and the following periarticular soft tissue disorders: plantar fasciitis, shoulder syndrome, trochanteric bursitis, and tennis/golf elbow.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

510(K) SUMMARY

The following information is provided as required by 21 CFR 807.92.

SUBMITTER	
Name and Address:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto, CA 94304
Contact Person:	Lynn Allman Sr. Director, Regulatory Affairs Phone: 650-424-5369 submissions.support@varian.com
Date Prepared:	03 August 2026

DEVICE	
Subject Device Name:	Halcyon, Ethos Radiotherapy System
Common/Usual Name:	Linear accelerator radiation therapy system
Product Code and Classification:	Medical charged-particle radiation therapy system IYE | 21 CFR 892.5050 | Class II

PREDICATE DEVICE	
Predicate Device Name:	Halcyon, Ethos Radiotherapy System (K252977)
Reference Device(s):	No reference devices were used in this submission.

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 Halcyon and Ethos Radiotherapy systems may be used in the delivery of radiation treatment for adults with the following non-cancerous medically refractory hyperproliferative disorders: Dupuytren's contracture, Ledderhose disease, heterotopic ossification, and keloids; and low dose radiotherapy for adults with non-cancerous medically refractory osteoarthritis; and the following periarticular soft tissue disorders: plantar fasciitis, shoulder syndrome, trochanteric bursitis, and tennis/golf elbow.

The modification to the Indications for use does not change the Intended Use of the device, as the general purpose of the device and its function remain the same. Additionally, the intended therapeutic use of the device remains the same - "to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated." As demonstrated by the risk management activities per ISO 14971, the differences do not affect the safety and effectiveness of the device when used as labeled.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Both subject device and predicate device contain the same technological characteristics and functional scientific technology to deliver radiation therapy and stereotactic radiosurgery by authorized medical practitioners. The Intended Use is unchanged. There are no changes in the principle of operation of the device. The biocompatibility of patient-contacting components remains the same as the predicate device. The results of the verification, validation and safety standards testing demonstrate that there are no changes to the safety profile of the device.

Both the predicate device and the subject device are based on the same characteristics:

Both the subject device and the predicate device configurations use the same medical linear accelerator (linac) to deliver stereotactic radiosurgery and precision radiotherapy and support the same treatment techniques.

- Both devices use the same couch and support the same couch motions.
- Both devices use the same integrated treatment and imaging consoles and support external beam radiation delivery.
- Both devices use the same muti-leaf collimators and support a range of imaging techniques.

The changes being addressed in this 510(k) are as follows:

Significant Change

- Modification of the indications for use of the device to add the following:

  "The Halcyon and Ethos Radiotherapy systems may be used in the delivery of radiation treatment for adults with the following non-cancerous medically refractory hyperproliferative disorders: Dupuytren's contracture, Ledderhose disease, heterotopic ossification, and keloids; and low dose radiotherapy for adults with non-cancerous medically refractory osteoarthritis; and the following periarticular soft tissue disorders: plantar fasciitis, shoulder syndrome, trochanteric bursitis, and tennis/golf elbow."

Non-significant Changes

- Defect fixes
- Magnetron identification implementation

PERFORMANCE DATA

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

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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The software for this device was considered as a "major" level of concern.

This submission leverages testing from both versions, HAL 5.0 and HAL 5.0 MR1 to ensure it contains the full performance testing of the system.

As HAL 5.0 MR1 consisted of non-significant changes which only affected a subset of the existing verification and validation testing of HAL 5.0, performance testing was repeated on only the affected subsystems, using the same testing scope, pass criteria, and methods as in the predicate HAL 5.0.

Non-significant changes included in this submission do not affect cybersecurity.

There was no change to patient-contact materials biocompatibility in this medical device. Therefore, no change occurred in conformance to ANSI/AAMI/ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1".

Human factors validation study was conducted according to the standard IEC 62366 to verify that Halcyon and Ethos Radiotherapy System v5.0 performs well as intended for the intended users, uses, and use environments.

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

STANDARDS

Halcyon and Ethos Radiotherapy Systems conform to the following FDA recognized 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

Standards Organization	Standard / Number and Date	Standard Name	FDA Recognition Number
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

CLINICAL TESTING

Systematic literature reviews were conducted to establish substantial equivalence to the predicate device. No animal or clinical tests are being submitted to establish substantial equivalence with the predicate device.

CONCLUSION

Halcyon and Ethos Radiotherapy System v5.0 is substantially equivalent to the predicate device. The intended use is the same. The modifications to the indications for use do not change the Intended Use of

the device, as the general purpose of the device and its function remain the same. There are no significant changes to the technological characteristics of the subject device. Therefore, it is substantially equivalent to the predicate device, and there are no new questions of safety and effectiveness. The results of verification and validation as well as conformance to relevant safety standards demonstrate that Halcyon and Ethos Radiotherapy Systems meet the safety and performance criteria and is substantially equivalent to the predicate device.