Varian Medical Systems Inc.
% Lynn Allman
Senior Director Regulatory Affairs
911 Hansen Way m/s E110
PALO ALTO, CA 94304

November 3, 2023

Re: K232113
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: October 5, 2023
Received: October 6, 2023

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,

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)*
K232113

Device Name
Halcyon and Ethos Radiotherapy System

Indications for Use *(Describe)*

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.

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.

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

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
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E-mail: submissions.support@varian.com
Date: 01 Nov 2023

Proprietary Name: Halcyon, Ethos Radiotherapy System

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 (K222941)

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 HyperSight 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. 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.
Significant Differences:	The significant difference compared to the predicate is to **remove** the limitation to simulation and planning for only ***adaptive*** radiation therapy for the CBCT images and to reflect this in the Indications for Use. There are no technological differences in this device compared with the predicate. Use of CBCT images for planning of adaptive treatments was covered in K222941. This 510(k) includes further data to demonstrate feasibility to produce primary treatment plans using the HyperSight imaging system that are clinically equivalent to plans generated from conventional and simulator CT images.
Non-clinical Testing:	There was no non-clinical testing performed related to the significant change in the device. Further cybersecurity information was provided to FDA including test reports, plan and summary report and labelling in the form of a Security White Paper to address the requirements of section 524B of the FD&C Act
Clinical Tests:	**Overview:** The following information was acquired as evidence for the safe use of HyperSight images for primary treatment planning: •Images comparing sim CT vs Halcyon CBCTp in 26 patients including 16 men and 10 women for different anatomical sites • Comparison of treatment plans (CT Sim-image based vs CBCTp image-based) for different anatomical sites created on those patients' images • Specifications of dose calculation such as DVH and other measurements that can be used to compare and validate these treatment plans **Summary of the testing:** A data set consisting of 26 human subject cases was obtained from three institutions in US and Europe utilizing HyperSight imaging in institutionally approved prospective single-site clinical studies. The clinical studies included adult patients who were planned to receive radiation therapy for conditions in the head/neck, thorax (including breast), abdomen, or pelvis. Both men and women and members of all races and ethnic groups were eligible for these trials. Prospective study participants were excluded due to pregnancy or plans for pregnancy during the clinical study, or due to an unwillingness or

inability to provide informed consent to participate in the study. For two institutions, CBCT images were obtained using the CBCTp workflow, while the third captured images with the IGRT workflow. HyperSight images covered the same area of the body that was being treated with radiotherapy. The 26 cases are the first 26 patients submitted to Varian across the three studies; no selection of cases was made for this analysis.

For each case, planning CT and HyperSight CBCT image sets, contours, and clinical planning objectives were provided to Varian along with a summary list identifying the dosimetrist and physician involved with each case. Varian created radiation treatment plans for each type of image separately, using a standardized planning approach (RapidPlan) available in the Varian Eclipse treatment planning system. Each type of plan (CT- and HyperSight-based) was evaluated against clinical objectives, consisting of

- target coverage goals and
- normal tissue constraints.

The clinical cases provide a range of commonly encountered anatomies from head to pelvis in actual clinical treatment conditions. In addition, these anatomies comprise a wide range of tissues to challenge the treatment planning tasks of organ segmentation and dose calculation, including metal artifacts (as in dentition, fiducials, or hip prosthesis). In regions where respiratory motion could occur (thorax and abdomen), breath-hold or a 5.9-second free-breathing CBCT acquisition was utilized to limit motion artifacts.

The acceptance criteria applied to the evaluation included the following:

- Patient-Specific QA
  - Ionization chamber measured dose ±3% as predicted by treatment planning system
  - 2D gamma analysis of predicted planar dose distribution as compared to measured signal from the portal imaging panel - at least 95% of analyzed points passed 3%/2mm gamma criteria

- Image Acquisition and Contouring
  - Successful creation of contours for each dataset
  - All relevant organs-at-risk and targets are discernable

- Treatment Plan Comparison
  - From established, published Clinical Goals for each anatomical site

No adverse events were reported or observed.

Overall Conclusion:
The test results demonstrate the feasibility of the Halcyon 4.0 with HyperSight imaging system to produce primary treatment plans that are clinically equivalent to plans generated from conventional and simulator CT images.

Standards Conformance: Halcyon and Ethos radiotherapy system conform to the same FDA recognised standards as the predicate device. See table below.

EN ISO 13485:2016.	Quality management systems. Requirements for regulatory purposes.
EN ISO 14971:2019.	Medical devices - Application of risk management to medical devices.
ISO 15223-1:2016.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
AAMI/ANSI/ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. (Biocompatibility)
IEC 62304: 2006+A1:2015	Medical device software - Software Life Cycle processes. (Software/Informatics)
IEC 62366-1:2015	Medical devices -Application of usability engineering to medical devices. (General I (QS/RM)).
ANSI / AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) + A1 2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance. (General)
IEC 60601-2-1:2020 (Edition 4.0)	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV. (Radiology).
IEC 60601-1-2:2014 (4th Edition)	General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (General II (ES/EMC))
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (General I (QS/RM))
IEC 60601-1-3 Edition 2.1 2013-042	Medical electrical equipment - Part 1-3 General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-68:2014.	Medical electrical equipment –Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
IEC 60601-2-44:2009+AMD1:2012+AMD2:2016).	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60976 Ed. 2.0 2007.	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics. (Radiology)
IEC 61217: 2011.	Radiotherapy equipment - Coordinates, movements, and scales. (Radiology)
IEC 62274: 2005	(FDA Consensus Standard), Medical electrical equipment - Safety of radiotherapy record and verify systems. (Radiology)
IEC 60825-1 Ed. 2.0 2007.	Safety of laser products - Part 1: Equipment classification, and requirements [Including: technical corrigendum 1 (2008), Interpretation sheet 1 (2007), Interpretation sheet 2 (2007)]. (Radiology)
AAMI RT2:2017	Radiation therapy readiness check

Argument for Substantial Equivalence to the Predicate Device:

Halcyon and Ethos Radiotherapy System in this submission are the same devices with the same intended use, techological characteristic specifications and non-clinical testing as cleared in the predicate device, K22941. Further clinical data have been supplied to FDA

to demonstrate the suitability of the device for acquiring CBCT images with HyperSight for use in primary radiotherapy treatment planning. This includes

- Images comparing sim CT vs Halcyon CBCTp in 26 patients including 16 men and 10 women for different anatomical sites
- Comparison of treatment plans (CT Sim-image based vs CBCTp image-based) for different anatomical sites created on those patients' images
- Specifications of dose calculation used to compare and validate these treatment plans.

The conclusion of the clinical testing is that, based on the results, Halcyon 4.0 with HyperSight imaging configuration, specifically for 125 and 140 kVp imaging energies, allows for creation of treatment plans that are equivalent in quality and accuracy of delivery to standard CT scanners.
Varian therefore believes that the expanded indications for use to include using HyperSight CBCT images for primary treatment planning does not affect the safety or effectiveness of the subject device compared to the predicate and therefore does not represent a new intended use or raise different questions of safety or effectiveness.

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. (K222941).
2. The device and its predicate have the same intended use.
3. The device and its predicate have the same technological characteristics.

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