Varian Medical Systems, Inc
℅ Peter Coronado
Senior Director, Varian Oncology Systems Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

January 17, 2023

Re: K222941
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: December 16, 2022
Received: December 16, 2022

Dear Peter Coronado:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 -S

Digitally signed by Lora D. Weidner -S
Date: 2023.01.17 14:10:55 -05'00'

Lora Weidner, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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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)*
K222941

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 adaptive 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.

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

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K222941

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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: Peter J. Coronado-Senior Director Regulatory Affairs
Phone: 650/424.6320
Fax: 650/646.9200
E-mail: submissions.support@varian.com
Date: 20 September 2022

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 (K192377)

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.

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 adaptive radiation therapy.

Significant differences:

The significant differences compared to the predicate are:

- **Cone Beam CT for Planning (CBCTp):** the Image Taker or Treater can acquire a kV CBCT that is used for the purpose of simulation and planning for adaptive radiation therapy. This software feature includes customizable CBCTp protocols, guided workflow, interactive isocenter placement, Patient marking and treatment position verification. Additionally, highly accurate HU specifications for dose calculation are included due to new spectrum-dependent HU calibration and accurate modeling of the imaging chain. This feature requires Advanced Imaging.

- **High Performance Imaging*:*** is a combination of new hardware and software that enables 6 second kV CBCT acquisition for improved image quality. Improved imaging quality is achieved by 6RPM gantry rotation during image acquisition, an all-new XL imager, new kV collimator with full fan bowtie filter, and larger capacity x-ray tube. Also included is new iCBCT-based metal artifact reduction and extended field of view (FOV) reconstruction out to 70 cm.

- **Beam-Hold Interface:** enables a validated external motion compensation system to send beam hold and release signals to HAL depending on the position or respiratory state of the patient.

- **Automatic mAs Detection:** This enables the system to automatically determine the optimal mAs (tube-current and time) to improve consistency of image quality

Non-clinical Testing

Verification of the capability of the modified software and hardware to produce CBCT images for Image Guided Radiotherapy and simulation and planning for adaptive radiation therapy was completed. Validation of the use of the modified CBCTp work flow was also performed. In addition, the image quality and dose calculation accuracy was assessed and compared with planning CT images for its suitability to support adaptive planning.
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, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
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

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

IEC 60601-1-3 Edition 2.1 2013-04
ANSI / AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) + A1 2012
IEC 60601-1-2:2014 (4th Edition)
IEC 60601-1-6 Edition 3.1 2013-10
IEC 60601-2-1:2020 (Edition 4.0)
IEC 60825-1 Ed. 2.0 2007
IEC 60976 Ed. 2.0 2007

IEC 61217: 2011
IEC 62274: 2005
IEC 62304: 2006
IEC 62366-1:2015
ISO 10993-1:2018
IEC 60601-2-68:2014
IEC 60601-2-44:2009+AMD1:2012+AMD2:
AAMI RT2:2017
ISO 15223-1:2016
EN ISO 14971:2019
EN 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) 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. The indications for use have been modified by the addition of the sentence "The Halcyon and Ethos Radiotherapy System produce CBCT images that can be used in Image Guided Radiation Therapy, and the simulation and planning for adaptive radiation therapy." 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 Halcyon and ethos radiotherapy System are substantially equivalent to the predicate.