February 10, 2020

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Senior Director, Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

Re: K192377
Trade/Device Name: Ethos Treatment Management, Ethos Treatment Planning, Ethos Radiotherapy System, and Halcyon
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: January 10, 2020
Received: January 13, 2020

Dear Mr. 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192377

Device Name
Ethos Treatment Management,
Ethos Treatment Planning,
Ethos Radiotherapy System, and Halcyon

Indications for Use *(Describe)*
Ethos Treatment Management is indicated for use in managing and monitoring radiation therapy treatment plans and sessions.

Ethos Treatment Planning is indicated for use in generating and modifying radiation therapy treatment plans.

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.

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

Ethos Treatment Management 2.0, Ethos Treatment Planning 1.0, Ethos Radiotherapy System 3.0 & Halcyon 3.0

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

Submitter's Name:

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto, CA 94304

Contact Name: Peter J. Coronado, Senior Director Regulatory Affairs
Phone: 650-424-6320 | Fax: 650-646-9200
E-mail: submissions.support@varian.com
Date Prepared: 29 August 2019

Proprietary Names:

Ethos Treatment Management
Ethos Treatment Planning
Ethos Radiotherapy System
Halcyon

Classification Name:

Medical charged-particle radiation therapy system
21 CFR 892.5050

Common/Usual Names:

Ethos Treatment Management	Treatment Plan and Image Management Application
Ethos Treatment Planning	Treatment Planning System
Ethos Radiotherapy System	Medical Linear Accelerator
Halcyon	Medical Linear Accelerator

Predicate Devices:

Ethos Treatment Management	ARIA Radiation Therapy Management (K173838)
Ethos Treatment Planning	Eclipse Treatment Planning System (K181145)
Ethos Radiotherapy System	Halcyon (K181032)
Halcyon	Halcyon (K181032)

Device Description:

Ethos Treatment Management	Ethos Treatment Management is software designed for radiation therapy medical professionals to support them in managing radiation treatments for patients.
Ethos Treatment Planning	Ethos Treatment Planning is software that is designed generate treatment plans, modify treatment plans, and guide users within adaptive treatment sessions.
Ethos Radiotherapy System	Halcyon and Ethos Radiotherapy System are single energy linacs designed to deliver Image Guided Radiation Therapy and radiosurgery, using Intensity Modulated and Volumetric Modulated Arc Therapy techniques. They consist of an accelerator and patient support within a radiation shielded treatment room and a control console outside the treatment room.
Halcyon	

Intended Use:

Ethos Treatment Management	Ethos Treatment Management is used to manage and monitor radiation therapy treatment plans and sessions; it is intended to be used with a treatment planning system.
Ethos Treatment Planning	Ethos Treatment Planning is used to generate and modify radiation therapy treatment plans.
Ethos Radiotherapy System (The intended use statement is identical to the predicate)	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.
Halcyon (The intended use statement is identical to the predicate)	

Indications for Use:

Ethos Treatment Management	Ethos Treatment Management is indicated for use in managing and monitoring radiation therapy treatment plans and sessions.
Ethos Treatment Planning	Ethos Treatment Planning is indicated for use in generating and modifying radiation therapy treatment plans.
Ethos Radiotherapy System	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	

Relationships Between the Devices:

1. The three devices of **Ethos Treatment Management**, **Ethos Treatment Planning**, and **Ethos Radiotherapy System** are used together within a radiation therapy treatment workflow. The overall clinical workflow involves each device performing a designated set of functions for radiotherapy treatment related to management, planning, and delivery which are best understood and described together.
2. **Ethos Radiotherapy System** and **Halcyon** are similar device models within a generic device type that share significant technological and functional characteristics.
3. For this Traditional 510(k) submission, these devices have been bundled together such that they can all be addressed during one review, given the shared scientific and regulatory considerations these devices raise.

Comparison of Technological Characteristics with the Predicate Device:

At a high level, each subject device and its corresponding predicate are similar based on the following characteristics:

Ethos Treatment Management

- Stand-Alone Software for Radiotherapy Management
- Support for Management and Monitoring Tools related to Radiation Treatment
- Support for Recording and Storing Treatment Parameters and Treatment Course Progression

Ethos Treatment Planning

- Stand-Alone Software for Radiotherapy Treatment Planning
- Support for Radiotherapy Treatment Planning with an External Beam Photon Delivery System
- Support for IGRT, IMRT, IMRS, VMAT Treatment Planning Techniques

Ethos Radiotherapy System

- Medical Linear Accelerator with Patient Support Couch
- Support for Radiotherapy Treatment using External Beam Photon Delivery
- Treatment Energy: 6 MV Flattening Filter Free
- Dose rate: Up to 800 MU/min
- Integrated Components: Treatment and Imaging Consoles, MLC, kV imager, Patient Camera, and others

Halcyon

- Medical Linear Accelerator with Patient Support Couch
- Support for Radiotherapy Treatment using External Beam Photon Delivery
- Treatment Energy: 6 MV Flattening Filter Free
- Dose rate: Up to 800 MU/min
- Integrated Components: Treatment and Imaging Consoles, MLC, kV imager, Patient Camera, and others

Significant Differences:

At a high level, each subject device and its corresponding predicate are different based on the following features:

Ethos Treatment Management

- Enhanced Work Areas and Tools for Users to specify Radiation Treatment Intent
- Enhanced Work Areas and Tools for Monitoring over the course of Radiation Treatment
- Compatibility with **Ethos Treatment Planning** and **Ethos Radiotherapy System**

Ethos Treatment Planning

- Support for Adaptive Radiotherapy Treatment Planning and Automated Plan Generation
- Support for Treatment Session Management with Guided Workflows and Work Areas
- Compatibility with **Ethos Treatment Management** and **Ethos Radiotherapy System**

Ethos Radiotherapy System

- Support for Adaptive Radiotherapy Treatment Delivery
- Compatibility with **Ethos Treatment Management** and **Ethos Treatment Planning**
- Patient Motion Monitoring & Extended Treatment Field Area

Halcyon

- Patient Motion Monitoring & Extended Treatment Field Area (same as in **Ethos Radiotherapy System**)

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

The software for these devices 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 were conducted for the linear accelerators. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

No animal studies or clinical tests have been included in this pre-market submission.

Standards Conformance:

The devices conform in whole or in part to the following recognised standards.

Applied Standard	Device Name		
IEC 62304	**Ethos Treatment Management**	**Ethos Treatment Planning**	**Ethos Radiotherapy System** and **Halcyon**
IEC 61217		**Ethos Treatment Planning**	**Ethos Radiotherapy System** and **Halcyon**
IEC 62274	**Ethos Treatment Management**		**Ethos Radiotherapy System** and **Halcyon**
IEC 62083	**Ethos Treatment Management**	**Ethos Treatment Planning**	
IEC 82304-1	**Ethos Treatment Management**	**Ethos Treatment Planning**	
IEC 62366-1	**Ethos Treatment Management**	**Ethos Treatment Planning**	
IEC 60825-1	Not applicable to the software devices		**Ethos Radiotherapy System** and **Halcyon**
IEC 60976			**Ethos Radiotherapy System** and **Halcyon**
IEC 60601-1			**Ethos Radiotherapy System** and **Halcyon**
IEC 60601-1-2			**Ethos Radiotherapy System** and **Halcyon**
IEC 60601-1-3			**Ethos Radiotherapy System** and **Halcyon**
IEC 60601-1-6			**Ethos Radiotherapy System** and **Halcyon**
IEC 60601-2-1			**Ethos Radiotherapy System** and **Halcyon**
IEC 60601-2-68			**Ethos Radiotherapy System** and **Halcyon**

Additional general (non-device specific) standards applied include:

- EN ISO 13485:2016 Edition 3 2016-03
  - Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012 2012-07
  - Medical devices – Application of risk management to medical devices
- ISO 15223-1 Third Edition 2016-11-01
  - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

Argument for Substantial Equivalence to the Predicate Device

A subset of technological characteristics and features of each of the current devices are different to their corresponding predicates. These differences are all considered by Varian to be enhancements of the predicate.

The Intended Use and indications for use are not significantly different. There are no changes in the principle of operation of the devices. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes that **Ethos Treatment Management**, **Ethos Treatment Planning**, **Ethos Radiotherapy System**, and **Halcyon** are substantially equivalent to their corresponding predicates.

Conclusion:

The assessment following the outcomes observed in the performance testing and software verification and validation was that these products conformed to the defined user needs and intended uses. There were no DRs (discrepancy reports) remaining which had a priority of Safety Intolerable or Customer Intolerable. Varian therefore considers **Ethos Treatment Management**, **Ethos Treatment Planning**, **Ethos Radiotherapy System**, and **Halcyon** to be safe and effective and to perform at least as well as the predicate device.