Varian Medical Systems, Inc.
% Mr. Peter Coronado
Sr. Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

August 20, 2021

Re: K212294
Trade/Device Name: Ethos Treatment Management, 2.1; Ethos Treatment Planning, 1.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: July 21, 2021
Received: July 22, 2021

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,

Michael D. O'Hara For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212294

Device Name
Ethos Treatment Management, 2.1
Ethos Treatment Planning, 1.1

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.

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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510(k) Summary

K212294

I. SUBMITTER

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Date Prepared: 16 Aug 2021

II. DEVICES

This is a bundled 510(k) for two devices: Ethos Treatment Management and Ethos Treatment Planning. The devices are submitted together to ensure that the shared scientific and regulatory considerations they raise are addressed within one review.

Trade name:	Ethos Treatment Management, version 2.1	Ethos Treatment Planning, version 1.1
Common name:	Treatment plan and image management application	Treatment planning system
Classification name:	Medical charged-particle radiation therapy system (21 CFR 892.5050)	Medical charged-particle radiation therapy system (21 CFR 892.5050)
Regulatory class:	Class II	Class II
Product code:	IYE	MUJ

III. PREDICATE DEVICES

Predicate device:	Ethos Treatment Management, version 2.0 (K192377)	Ethos Treatment Planning, version 1.0 (K192377)

The predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTIONS

Device Description:	Ethos Treatment Management is a standalone software device designed to help radiation therapy medical professionals manage treatments for their patients. It allows the physician to do initial planning, review and approve candidate plans, and monitor ongoing treatments.	Ethos Treatment Planning is a standalone software device designed to generate and modify radiation therapy treatment plans and manage treatment sessions. The device supports the traditional and adapted treatments, in which the scheduled plan is adapted to the patient's anatomy at the time of treatment.
Compatibility	Ethos Treatment Management and Ethos Treatment Planning are only compatible with Ethos Radiotherapy System/Halcyon.	

V. INTENDED USE AND INDICATIONS FOR USE

Intended Use:	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. *(Same as predicate)*	Ethos Treatment Planning is used to generate and modify radiation therapy treatment plans. *(Same as predicate)*
Indications for Use:	Ethos Treatment Management is indicated for use in managing and monitoring treatment plans and sessions. *(Same as predicate)*	Ethos Treatment Planning is indicated for use in generating and modifying radiation therapy treatment plans. *(Same as predicate)*

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Ethos Treatment Management and Ethos Treatment Planning have the same technological characteristics as their predicate devices. A subset of features of the new devices is different; the significant changes are the automatic handling of the resumption plans (both devices) and the capability to overlay planning CT and session CBCT to compare patient's anatomy and verify isocenter location (Ethos Treatment Management only). The changes are minor enhancements of the predicates that cannot be considered different technological characteristics. There are no substantial changes in the principle of operation of the software or in the core algorithms.

VII. PERFORMANCE DATA

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

Software Verification and Validation Testing

Software verification and validation were conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management System standard and other FDA recognized consensus standards listed below. Test results showed that applicable requirements were met and assured that safeguards against hazards functioned properly.

The documentation in the submission was provided as recommended by the FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005). The level of concern for both devices is **major** because a failure or latent flaw in the software could directly result in serious injury or death to the patient or the operator.

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

Standards Conformance

The devices conform with the following standards:

- IEC 62304:2006/A1:2015 Medical device software – Software lifecycle processes
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 62083:2009 Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
- IEC 82304-1:2016 Health software – Part 1: General requirements for product safety
- AAMI RT2:2017 Radiation therapy readiness check
- IEC 62274:2005 Medical electrical equipment – Safety of radiotherapy record-and-verify systems (Ethos Treatment Management only)
- IEC 61217:2011 Radiotherapy equipment – Coordinates, movements, and scales (Ethos Treatment Planning only)

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

- EN ISO 13485:2016 Medical devices – 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, labeling, and information to be supplied

VIII. CONCLUSIONS

Since the predicate devices were cleared based only on the results of non-clinical testing, no animal or clinical studies were conducted for the subject devices. The non-clinical data support the safety of the device, and the software verification and validation demonstrate that Ethos Treatment Management and Ethos Treatment Planning should perform as intended in the specified use conditions. Ethos Treatment Management and Ethos Treatment Planning are as safe and effective as the predicates that are currently marketed for the same intended use.