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

July 10, 2020

Re: K201607
Trade/Device Name: Eclipse Treatment Planning System, v16.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: June 10, 2020
Received: June 15, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201607

Device Name
Eclipse Treatment Planning System, v16.1

Indications for Use *(Describe)*
The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments.

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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Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

K201607

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:	Peter J. Coronado Sr. Director, Regulatory Affairs Phone: 650-424-6320 | Fax: 650-646-9200 submissions.support@varian.com
Date Prepared:	10 June 2020

DEVICE	
Subject Device Name:	Eclipse Treatment Planning System v16.1
Common/Usual Name:	Eclipse Treatment Planning System (Eclipse TPS)
Product Code and Classification:	Medical charged-particle radiation therapy system MUJ | 21 CFR 892.5050 | Class II

PREDICATE DEVICE	
Predicate Device Name:	Eclipse Treatment Planning System v16.0 (K200608)
Reference Device(s):	No reference devices were used in this submission.

DEVICE DESCRIPTION

The Varian **Eclipse™ Treatment Planning System** (Eclipse TPS) provides software tools for planning the treatment of malignant or benign diseases with radiation. Eclipse TPS is a computer-based software device used by trained medical professionals to design and simulate radiation therapy treatments. Eclipse TPS consists of different applications, each used for specific purposes at a different phase of treatment planning.

Eclipse TPS is capable of planning treatments for external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation (brachytherapy) treatments.

INDICATIONS FOR USE

The **Eclipse Treatment Planning System** (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified device, referred to as the "subject device" throughout this summary, is release version v16.1 (version 16.1) of the Eclipse Treatment Planning System with additional software changes incorporated since the release version of the predicate device, version 16.0 (K200608).

At a high level, both the predicate device and the subject device are based on the same characteristics:

- Both the subject device and the predicate provide software tools for planning the treatment of malignant or benign diseases with radiation.
- They are computer-based software devices used by trained medical professionals to design and simulate radiation therapy treatments.
- They are both capable of planning treatments for external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation (brachytherapy) treatments.

The following differences exist between the software release versions of the subject and the predicate devices:

The significant changes compared with the predicate device are as follows:

1. Graphics processing unit (GPU) calculation can be used for the Acuros PT dose calculation.
2. Dual Energy Computed Tomography (DECT) images can be used in calculation of proton stopping power.
3. Preventing dose calculation for DECT Rho and Z images.

Other changes compared with the predicate device are detailed in the document_" Predicate Comparison and Summary of Design Control Activities" in the Executive Summary section of this submission.

PERFORMANCE DATA

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

Software Verification and Validation Testing

Software verification and validation was 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.

Test results demonstrate conformance to applicable requirements and specifications.
No animal studies or clinical tests have been included in this pre-market submission.

Standards conformance

The subject device conforms in whole or in part with the following standards:

- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.0 2015-02 Application of usability engineering to medical devices
- IEC 61217 Edition 2.0 2011-12 Radiotherapy equipment - Coordinates, movements, and scales
- IEC 62083 Edition 2.0 2009-09 Requirements for the safety of radiotherapy treatment planning systems
- IEC 82304-1 Edition 1.0 2016-10 Health software - Part 1: General requirements for product safety

Argument for substantial equivalence to the predicate device

A subset of software features and characteristics of the subject device are different from the predicate device. However, Varian considers these differences to be enhancements of the predicate. The principle of operation of the subject device is the same as that of the existing predicate device. Verification and validation demonstrate that the subject device is as safe and effective as the predicate. Varian therefore believes that the subject device is substantially equivalent to the predicate device.

CONCLUSION

The predicate device was cleared based only on non-clinical testing, and no animal or clinical studies were performed for the subject device. The non-clinical data supports the safety of the device, and verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. There were no remaining discrepancy reports (DRs) which could be classified as Safety or Customer Intolerable.
Therefore, Varian considers **Eclipse Treatment Planning System v16.1** to be safe and effective and perform at least as well as the predicate device, **Eclipse Treatment Planning System 16.0 (K200608)**.