



December 11, 2024

Varian Medical Systems
Lynn Allman
Sr. Director Regulatory Affairs
3100 Hansen Way
Palo Alto, California 64304

Re: K242378

Trade/Device Name: Eclipse Treatment Planning System (18.1)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: August 9, 2024
Received: August 9, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

A handwritten signature in black ink, appearing to read "Lora D. Weidner". The signature is fluid and cursive. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

Indications for Use

Submission Number (if known)

K242378

Device Name

Eclipse Treatment Planning System (18.1)

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 radiation (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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Eclipse Treatment Planning System v18.1

Legally Marketed Equivalent Device (Predicate)

Product: Eclipse Treatment Planning System v18.0

510(k) Number: K230557

Intended 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 radiation (brachytherapy) treatments.

There is no change in intended use between the predicate and subject device.

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Lynn, Allman, PhD., Senior Director Regulatory Affairs
Phone: (650) 424-5369
E-mail: submissions.support@varian.com
Date Prepared: August 9, 2024

II. Device Information

Proprietary Name: Eclipse Treatment Planning System v18.1
Classification Name: Medical charged-particle radiation therapy system
Regulation Number: §892.5050
Product Code: MUJ

III. Predicate Device

Eclipse Treatment Planning System v18.0 (K230557)

IV. Device Description

Eclipse provides software tools for planning the treatment of malignant or benign diseases with radiation. Eclipse is a computer-based software device used by trained medical professionals to design and simulate radiation therapy treatments. It is capable of planning treatments for external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation (brachytherapy) treatments.

Eclipse is used for planning external beam radiation therapy treatments employing photon energies between 1 and 50 MV, electron energies between 1 and 50 MeV, for proton energies between 50 and 300 MeV, and for planning internal radiation (brachytherapy) treatments with any clinically approved

510(k) Summary

Traditional 510(k) Application
Eclipse Treatment Planning System

radioisotope. The treatment planning system utilizes a patient model or virtual patient derive from medical imaging techniques to simulate, calculate and optimize the radiation dose distribution inside the body during a treatment procedure in order to ensure effective treatment of the tumor but to minimize damage to surrounding tissue.

V. Comparison of Technological Characteristics with the Predicate Device

The modified device, referred to as the “subject device” throughout this summary, is release version v18.1 (version 18.1) of the Eclipse Treatment Planning System with additional software changes incorporated since the release version of the predicate device, version 18.0 (K230557).

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.

RapidScan and RapidArc Dynamic are new features and are described below:

- **RapidScan:** RapidScan is an integrated proton therapy solution between Eclipse Treatment Planning System and ProBeam Proton Delivery System. It offers control over more parameters during treatment planning and provides enhanced feedback on plan quality and field-wise delivery times.
- **RapidArc Dynamic:** RapidArc Dynamic is an improved optimization algorithm that enables the benefits of a dynamic collimator, directional control of IMRT and efficiency of VMAT in a single solution. RapidArc Dynamic allows static gantry angle modulation to be incorporated with VMAT using a single optimization algorithm, increasing the quality of the plan while minimally impacting planning and treatment delivery time compared to VMAT only treatments.

The changes being addressed in this 510(k):

- Significant changes
 - RapidArc Dynamic
 - RapidScan
 - Support of Multiple Institutions
 - Enhanced calibration curve support
 - Enabling volume of interest for Proton AcurosPT
 - AcurosPT SFO dose optimization
 - Plan Checker
- Non-significant changes
 - Enabling Proton ESAPI intermediate dose
 - Updates to RT Peer Review
 - Core algorithm updates

510(k) Summary

Traditional 510(k) Application
Eclipse Treatment Planning System

VI. Summary of Performance Testing (Non-Clinical Testing)

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.

Cybersecurity and Interoperability requirements were assessed per FDA guidance's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Sept 2023)", "Postmarket Management of Cybersecurity in Medical Devices (Jan 2016)", "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices (Jan 2016)".

Testing of new features in Eclipse TPS 18.1 followed a multi-level test approach, through unit, integration, and system (end-to-end) level testing. Testing to support that new features in Eclipse TPS 18.1 are comparable to the predicate device was performed through measurement comparison tests using Gamma evaluation criteria, plan comparisons using clinical objectives and workflow testing.

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

Use of Consensus Standards:

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Information supplied by the manufacturer of medical devices
IEC 62304:2006 + A1:2016	Medical Device Software - Software Lifecycle processes
IEC 62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
IEC 82304-1:2016	Health software Part 1: General requirements for product safety
AAMI RT2:2017	Radiation Therapy Readiness Check
IEC 61217:2011	Radiotherapy Equipment, Coordinates, Movements and Scales
IEC 62083:2009	Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
UL ANSI 2900-1:2017	Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
UL ANSI 2900-2-1:2017	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

510(k) Summary

Traditional 510(k) Application
Eclipse Treatment Planning System

VII. Determination of Substantial Equivalence to the Predicate

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.