



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

May 26, 2023

Re: K230557

Trade/Device Name: Eclipse Treatment Planning System (v18.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: February 27, 2023
Received: February 28, 2023

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: 2023.05.26
12:52:05 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K230557

Device Name
Eclipse Treatment Planning System (v18.0)

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.

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510(k) SUMMARY

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

K230557

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
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Date Prepared: 27 February 2023

DEVICE

Subject Device Name: Eclipse Treatment Planning System v18.0
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 v16.1 (K201607)
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 v18.0 (version 18.0) of the Eclipse Treatment Planning System with additional software changes incorporated since the release version of the predicate device, version 16.1 (K201607).

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:

Proton dose calculation changes:

- Proton Monte Carlo optimization
- Proton treatment time calculation
- Proton fast particle generation

Photon dose calculation and evaluation changes:

- General SBRT normal tissue objective (NTO)
- Enhanced leaf tip modeling
- Speed improvement of GPU source model
- FTDC Fourier transformation dose calculator improvements
- Multi-criteria optimization (MCO) isodose line dragging

Other changes:

- UI support for treatment site
- Brachytherapy dwell control improvements

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 82304-1 Edition 1.0 2016-10 Health software - Part 1: General requirements for product safety
- IEC 62083 Edition 2.0 2009-09 Requirements for the safety of radiotherapy treatment planning systems
- IEC 61217 Edition 2.0 2011-12 Radiotherapy equipment - Coordinates, movements, and scales
- ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied
- ISO 20417:2021 Information supplied by the manufacturer of medical devices
- ISO 14971:2019+A1:2021 Medical devices - Application of risk management to medical devices
- EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

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 v18.0** to be safe and effective and perform at least as well as the predicate device, **Eclipse Treatment Planning System 16.1 (K201607)**.