May 16, 2025

Varian Medical Systems
Lynn Allman
Sr. Director Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K250099
Trade/Device Name: Mobius3D (4.1)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: January 14, 2025
Received: January 14, 2025

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250099

Device Name

Mobius3D (4.1)

Indications for Use *(Describe)*

Mobius3D software is used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy. It calculates radiation dose three dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system, and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data. Patient alignment and anatomy analysis is based on read-in treatment planning images (such as computed tomography) and read-in daily treatment images (such as registered cone beam computed tomography).

Mobius3D is not a treatment planning system. It is to be used only by trained radiation oncology personnel as a quality assurance tool.

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.

K250099

Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Mobius3D 4.1.

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: January 14, 2025

II. Device Information

Proprietary Name: Mobius3D 4.1
Classification Name: Accelerator, Linear, Medical
Regulation Number: §892.5050
Product Code: IYE

III. Predicate Device

Mobius3D 4.0 (K203669)

There is no change in intended use.

IV. Device Description

Mobius3D is a software product used within a radiation therapy clinic for quality assurance and treatment plan verification. It is important to note that while Mobius3D operates in the field of radiation therapy, it is neither a radiation delivery device (e.g. a linear accelerator), nor is it a Treatment Planning System (TPS). Mobius3D cannot design or transmit instructions to a delivery device, nor does it control any other medical device. Mobius3D is an analysis tool meant solely for quality assurance (QA) purposes when used by trained medical professionals. Being a software only QA tool, Mobius3D never comes into contact with patients.

V. Intended Use

Mobius3D software is used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy. It calculates radiation dose three-dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data. Patient alignment and anatomy analysis is based on read-in treatment planning images (such as computed tomography) and read-in daily treatment images (such as registered cone beam computed tomography).

Mobius3D is not a treatment planning system. It is only to be used by trained radiation oncology personnel as a quality assurance tool.

VI. Comparison of Technological Characteristics with the Predicate Device

The modified device, referred to as the "subject device" throughout this summary, is release version 4.1 of the Mobius3D with additional software changes incorporated since the release version of the predicate device, version 4.0 (K203669).

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 are used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy.
- They are computer-based software devices used by trained medical professionals for treatment planning quality assurance.

The changes being addressed in this 510(k):

- Update to labeling: additional warnings
- RapidArc Dynamic Support
- Establish requirement for load capabilities for Dell Standard and Megaserver
- Recurring automated partial data wipe to reduce database size and increase performance
- Ubuntu OS upgrade
- Upgrade CouchDB
- Implement Department of Defense (DoD) and Varian Shared Requirements
- Improvement to ClamAV virus scanner
- Implement new Dell hardware platform
- Improve Varian MLC modelling
- Show server function
- Dynamic about box
- Removed features
    - Dose Lab Viewer Module
    - SmartConnect

VII. 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.

Testing for new and modified features followed a multi-level test approach including unit tests, integration tests, and end to end testing. MLC Modelling Accuracy testing was performed on a sequence of artificial and clinical plans for multiple energies and fluence modes comparing Mobius3D 4.0.2 (last release), Mobius3D 4.1 (current submission), measurement and Eclipse TPS 16.1 (Treatment Planning System). For new and modified features influencing the accuracy of dose calculation results, studies and reviews have been performed to assess the accuracy of newly introduced features and modifications:

a. Rapid Arc Dynamic Support
b. MLC Tongue and Groove Modelling

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)".

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 + A1:2015	Medical Device Software - Software Lifecycle processes
IEC 62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
IEC 61217:2011	Radiotherapy Equipment, Coordinates, Movements and Scales
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
IEC 81001-5-1:2021	Health Software and Health IT Systems Safety, Effectiveness and Security - Part 5-1: Security - Activities In The Product Life Cycle

VIII. 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.