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

October 23, 2024

Re: K241876
Trade/Device Name: Vitesse (5.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: September 23, 2024
Received: September 24, 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,

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)*

K241876

Device Name

Vitesse (5.0)

Indications for Use *(Describe)*

Vitesse is indicated for use as a treatment planning software application used by medical professionals to plan,guide,optimize and document high-dose-rate brachytherapy procedures

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.

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510(k) Summary

The following information is provided as required by 21 CFR 807.92

Submitter

Name and Address:	Varian Medical Systems, Inc. 3100 Hansen Way, Palo Alto CA 94304
Contact Person:	Lynn Allman, Senior Director Regulatory Affairs
E-mail:	submissions.support@varian.com
Date Prepared:	27 June 2024

Device Information:

Proprietary Name:	Vitesse 5.0
Common/ Usual Name:	System, Image Processing, Radiological
Product Code and Classification:	Medical charged-particle radiation therapy system MUJ |21 CFR 892.5050 |Class II

Predicate Device:

Predicate Device Name:	VITESSE 3.0 (K123152)

Subject Device Description:

The Varian **VITESSE 5.0** is a stand-alone application which provides treatment planning features for high dose rate brachytherapy. Vitesse supports real-time ultrasound guided implant procedures as well as image import based workflows based on DICOM RT. Vitesse supports DICOM RT export of the plan to another external dose planning system (e.g., Brachy Vision) or directly to the brachytherapy afterloader treatment unit.

Intended Use/ Indications of Use Statement:

Vitesse is intended for use as a treatment planning software application used by medical professionals to plan, guide, optimize and document high-dose-rate brachytherapy procedures. Vitesse is indicated for use as a treatment planning software application used by medical professionals to plan, guide, optimize and document high-dose-rate brachytherapy procedures.

Comparison of Technological Characteristics with the predicate device

The modified device, referred to as the subject device throughout this summary, is Vitesse (Version 5.0) with additional software changes incorporated since the release of the predicate device, Vitesse 3.0

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

- Both the subject device and the predicate device Both the devices are software only medical devices.

- Both devices perform treatment planning, provide tools for qualified medical professionals to manage treatment sessions and adapt plans for patient to be treated with radiation therapy.
- Both are compatible with radiation therapy devices.

The key changes exist between the subject and the predicate device.

- Vitesse will require the user to enter valid Windows credentials and permissions prior to accessing Vitesse.
- Provide more direct visualization of region definitions on the main UI. Currently, region definitions can only be visualized in a separate dialog.
- Provide the user with the ability to export a plan directly to a DICOM destination (e.g., Aria, Velocity) over the network (DICOM C-STORE).
- Provide the user with the ability to populate key elements of the patient record from the data in Aria via DICOM query (DICOM C-FIND).
- Provide support for import of common Enhanced MR DICOM images (i.e., standard images with orthogonal volumes).
- Provide support for import of PET DICOM images as secondary image volumes.
- Provides support for capturing color images. This allows images generated with color doppler and other color imaging modes to be captured in Vitesse and displayed as color images.

Other minor changes:
Version 5.0

- DR Fixes and product improvements
- Structure margins previewed on sagittal / coronal planes as well as transverse.
- Autosave supported on all running instances of Vitesse, not just first.
- Autosave files not rejected by the user are sent to recycle bin and not deleted.
- Batch margining of structures

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**

The subject device is considered under the Enhanced documentation category.
Software verification and validation testing for Vitesse 5.0 demonstrates that the device requirements and risk control measures perform as intended at a level similar to the predicate.

The subject device and the predicate device have the same intended use, and the significant differences do not result in a new intended use. Varian, therefore, believes that Vitesse 5.0 Treatment Planning is substantially equivalent to the predicate.

Software verification was conducted in accordance with IEC 62304 – "Medical device software - Software life cycle processes" and FDA guidance "Content of Premarket Submissions for Device Software Functions (June 2023)".

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)".

Cybersecurity considerations related to the subject device are included within this submission. Varian Medical Systems conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

Usability testing was conducted according to the standard IEC 62366 to verify that the subject device performs well as intended for the intended users, uses, and use environments.

Method of Evaluation

New or Modified Feature	**Method of Evaluation**
Provide the user with the ability to export a plan directly to a DICOM destination (e.g., Aria, Velocity) over the network (DICOM C-STORE).	Software verification and validation covering the performance and use of this feature
Provide the user with the ability to populate key elements of the patient record from the data in Aria via DICOM query (DICOM C-FIND)	Software verification and validation covering the performance and use of this feature
Vitesse will require the user to enter valid Windows credentials and permissions prior to accessing Vitesse	Software verification and validation covering the performance and use of this feature
Provide more direct visualization of region definitions on the main UI	Software verification and validation covering the performance and use of this feature

Provide support for PET images as secondary image volumes	Software verification and validation covering the performance and use of this feature
Provides support for import of PET DICOM images as secondary image volumes	Software verification and validation covering the performance and use of this feature
Provides support of capturing color images. This allows images generated with color doppler and other color imaging modes to be captures in Vitesse and displayed as color images	Software verification and validation covering the performance and use of this feature

- **Clinical Testing**

No clinical studies were carried out for the subject device and therefore, no such clinical data is provided within this submission.

- **Animal Testing**

No animal testing was conducted for the subject device and therefore, no such data is provided within this submission

- **Standards conformance**
  - ISO 14971:2019 Medical devices - Application of risk management to medical devices
  - 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
  - IEC 62366-1 Edition 1.0 2015-02 Application of usability engineering to medical devices
  - 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.
  - IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
  - EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

Conclusion

Overall, the subject device and the predicate device have the same intended use and indications for use. There is no change to the principle of operation of the device. The differences between the subject and predicate do not result in a new intended use and do not raise new questions of safety and effectiveness. The non-clinical data, verification and validation demonstrate that the subject device is as safe and effective as the predicate device and perform as intended. therefore, Varian believes that the subject device Vitesse 5.0 is substantially equivalent to the predicate device.