



December 13, 2024

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

Re: K242463

Trade/Device Name: ARIA Radiation Therapy Management System (18.1)

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical Charged-Particle Radiation Therapy System

Regulatory Class: Class II

Product Code: IYE

Dated: November 15, 2024

Received: November 15, 2024

Dear Dr. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lora Weidner". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

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)

K242463

Device Name

ARIA Radiation Therapy Management System (18.1)

Indications for Use (Describe)

The ARIA Radiation Therapy Management product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Therapy Management also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed 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.

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## Premarket Notification - 510(k) Summary

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Traditional 510(k) Submission for ARIA Radiation Therapy Management System v18.1

### Legally Marketed Equivalent Device (Predicate)

**Product:** ARIA Radiation Therapy Management System v18.0

**510(k) Number:** K230699

**Intended Use:** The ARIA Radiation Therapy Management product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Therapy Management also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed 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](mailto:submissions.support@varian.com)

Date Prepared: August 19, 2024

#### **II. Device Information**

Proprietary Name: ARIA Radiation Therapy Management System v18.1

Classification Name: Medical charged-particle radiation therapy system

Regulation Number: §892.5050

Product Code: MUJ

#### **III. Predicate Device**

ARIA Radiation Therapy Management System v18.0 (K230699)

#### **IV. Device Description**

ARIA Radiation Therapy Management (ARIA RTM) manages several treatment information such as images and treatment data to prepare plans created for treatment and review post-treatment images and records. It also provides quality assurance options.

ARIA RTM does not directly act on the patient. ARIA RTM is applied by trained medical professionals in the process of preparation and management of radiotherapy treatments for patients.

### **510(k) Summary**

Traditional 510(k) Application

ARIA Radiation Therapy Management System

**V. Intended Use**

The ARIA Radiation Therapy Management product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Therapy Management also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments.

**VI. 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 ARIA Radiation Therapy Management System with additional software changes incorporated since the release version of the predicate device, version 18.0 (K230699).

The changes in the subject device are as follows:

- Dynamic Collimator Support
- Multi-Institution
- Integrated Patient Setup Documentation (CTH Integration)
- Enhanced Calibration Curve Support

**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.

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

**510(k) Summary**

Traditional 510(k) Application  
ARIA Radiation Therapy Management System

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
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.