Varian Medical Systems, Inc
℅ Mr. Peter Coronado
Senior Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

Re: K221408
Trade/Device Name: ARIA Radiation Therapy Management (v16.1 MR3)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: May 13, 2022
Received: May 16, 2022

Dear Mr. 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,

for

Julie Sullivan, Ph.D.
Assistant Director
Radiation Therapy Team
DHT 8C: 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221408

Device Name
ARIA Radiation Therapy Management (v16.1 MR3)

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.

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

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# 510(k) Summary

K221408

## I. SUBMITTER

**Name and Address:** Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304

**Contact Person:** Peter J. Coronado
Sr. Director, Regulatory Affairs
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submissions.support@varian.com

**Date Prepared:** 13 May 2022

## II. DEVICE

| | |
|---|---|
| **Trade name:** | ARIA Radiation Therapy Management, version 16.1 MR3 |
| **Common name:** | ARIA Radiation Therapy Management |
| **Classification name:** | Medical charged-particle radiation therapy system<br>(21 CFR 892.5050) |
| **Regulatory class:** | Class II |
| **Product code:** | IYE |

## III. PREDICATE DEVICE

**Predicate Device:** ARIA Radiation Therapy Management, version 15.5 (K173838)

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

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. ARIA Radiation Therapy Management supports the integration of all data and images in one central database including archiving and restoration. The different ARIA Radiation Therapy Management features support the visualization, processing, manipulation and management of all data and images stored in the system. Images can also be imported through the network using DICOM, the available image import filters or by means of film digitizers.

## V. INTENDED USE AND INDICATIONS FOR 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.
*(Same as predicate)*

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The main changes in the subject device compared with the predicate device are as follows:

- The prevention of couch position edits after treatment approval and the prevention of inconsistent couch value editing
- Other improvements and enhancements of existing features:
    - Support for In-room CT
    - Structures ID extension to 64 characters
    - Shift extraction service
    - Implementation of Treatment Delivery Workflow II Treatment Delivery Protocol
    - Dynamic About Box
- Obsolescence of Matrox and Vidar filters

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

**Software Verification and Validation Testing**

Software verification and validation were conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management System standard and other FDA recognized consensus standards listed below. Test results showed that applicable requirements were met and assured that safeguards against hazards functioned properly.

The documentation in the submission was provided as recommended by the FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005). The level of concern is **major** because a failure or latent flaw in the software could directly result in serious injury or death to the patient or the operator.

No data from animal studies or clinical tests have been included in this pre-market submission.

**Standards Conformance**

ARIA Radiation Therapy Management conforms to the following regulatory standards including FDA recognized standards and references additional standards as applicable.

The devices conform with the following standards:

- IEC 62304:2006+A1:2015 Medical device software – Software lifecycle processes
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 82304-1:2016 Health software – Part 1: General requirements for product safety
- IEC 62274:2005 Medical electrical equipment – Safety of radiotherapy record-and-verify systems

- IEC 61217:2011 Radiotherapy equipment – Coordinates, movements, and scales

ARIA RTM was designed and developed, including verification and validation testing, within an established Quality System compliant to the following additional general (non-device-specific) standards:

- EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN 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, labeling, and information to be supplied
- EN ISO 20417:2021 – Information Supplied by the manufacturer of medical devices
- 21 CFR §820 – Quality System Regulation

## VIII. CONCLUSIONS

Since the predicate device was cleared based only on the results of non-clinical testing, no animal or clinical studies were conducted for the subject device. The non-clinical data support the safety of the device, and the software verification and validation demonstrate that ARIA Radiation Therapy Management should perform as intended in the specified use conditions. ARIA Radiation Therapy Management is as safe and effective as the predicate that is currently marketed for the same intended use.