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

Re: K221448
Trade/Device Name: ARIA Radiation Therapy Management (v15.8), Eclipse Treatment Planning System (v15.8)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: May 17, 2022
Received: May 18, 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)*
K221448

Device Name
ARIA Radiation Therapy Management (v15.8)

Eclipse Treatment Planning System (v15.8)

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.

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. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.

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

K221448

I. SUBMITTER

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Palo Alto, CA 94304

Contact Person: Peter J. Coronado
Sr. Director, Regulatory Affairs
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Date Prepared: 17 May 2022

II. DEVICES

This is a bundled 510(k) for two devices: ARIA Radiation Therapy Management and Eclipse Treatment Planning System. The devices are submitted together to ensure that the shared scientific and regulatory considerations they raise are addressed within one review.

Trade name:	ARIA Radiation Therapy Management, version 15.8	Eclipse Treatment Planning System, version 15.8
Common name:	ARIA Radiation Therapy Management	Treatment planning system, Eclipse
Classification name:	Medical charged-particle radiation therapy system (21 CFR 892.5050)	Medical charged-particle radiation therapy system (21 CFR 892.5050)
Regulatory class:	Class II	Class II
Product code:	IYE	MUJ

III. PREDICATE DEVICES

	ARIA Radiation Therapy Management	Eclipse Treatment Planning System
Predicate device:	ARIA Radiation Therapy Management, version 15.5 (K173838)	Eclipse Treatment Planning System, version 15.6 (K181145)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTIONS

	ARIA Radiation Therapy Management	Eclipse Treatment Planning System
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.	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 is capable of planning treatments for external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation (brachytherapy) treatments.

V. INTENDED USE AND INDICATIONS FOR USE

	ARIA Radiation Therapy Management	Eclipse Treatment Planning System
Indications for Use/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. *(Same as predicate)*	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. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye. *(Same as predicate)*

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Significant Differences

ARIA Radiation Therapy Management and Eclipse Treatment Planning System have the same technological characteristics as their predicate devices. All features are the same except for the following significant changes:

- Implementation of multi-institution support with cloud hosted Eclipse TPS and ARIA RTM.
- Changes in user workflow in support of multi-institution capability
- The prevention of couch position edits after treatment approval and the prevention of inconsistent couch value editing (ARIA RTM only)

Both the new devices and the predicate devices provide tools for qualified medical professionals to do initial planning, review and approve candidate plans, and monitor ongoing treatments for patients to be treated with radiation therapy. There are no substantial changes in the principle of operation of the software or in the core algorithms.

VII. PERFORMANCE DATA

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

Software Verification and Validation Testing

ARIA Radiation Therapy Management and Eclipse Treatment Planning System were verified and validated according to the FDA Quality System Regulation (21 CFR §820) and other FDA recognized consensus standards listed below. Test results demonstrate that the device conforms to design specifications and meets the needs of the intended users, including assuring risk mitigations were implemented and functioned properly. Software verification and validation testing were completed and documented 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 level of concern for both devices 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.

Standards Conformance

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 62083:2009 Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems (Eclipse Treatment Planning Only)
- 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 (ARIA Radiation Therapy Management only)
- IEC 61217:2011 Radiotherapy equipment – Coordinates, movements, and scales

Additional general (non-device-specific) standards applied include:

- 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 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied
- BS EN 1041:2008+A1:2013 – Information Supplied by the manufacturer of medical devices

VIII. CLINICAL TESTING

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

IX. CONCLUSIONS

ARIA Radiation Therapy Management 15.8 and Eclipse Treatment Planning System 15.8 are substantially equivalent to ARIA Radiation Therapy Management 15.5 and Eclipse Treatment Planning System 15.6 respectively. The intended use and indications for use are the same. The major technological characteristics are substantially equivalent to the predicate devices, and the differences do not raise new questions of safety and effectiveness. The results of verification and validation as well as conformance to relevant safety standards demonstrate that ARIA Radiation Therapy Management 15.8 and Eclipse Treatment Planning System 15.8 meet safety and performance criteria and are substantially equivalent to their predicate devices.