Varian Medical Systems, Inc.
% Mr. Peter Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
Palo Alto CA 94304

January 17, 2018

Re: K173838
Trade/Device Name: ARIA Radiation Therapy Management
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 15, 2017
Received: December 18, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173838

Device Name
ARIA Radiation Therapy Management

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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Premarket Notification [510(k)] Summary

ARIA Radiation Therapy Management 15.5 MR1

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: December 15, 2017
Proprietary Name:	ARIA Radiation Therapy Management
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050, Class II Product Code: IYE
Common/Usual Name:	ARIA Radiation Therapy Management
Predicate Devices:	ARIA Radiation Therapy Management (K133572)
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
Intended Use Statement	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.
Indications for Use Statement	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.

Technological Characteristics: Changes to the predicate device are listed below:

- Support for Brachy Manual Treatment
- Shared framework integration

- Support for multi-fractionation is removed
- Support for Siemens mArc, Hyperarc plans, and proton treatment machines
- Secondary Channel Integrity Check version 3 support
- Visualization of MLC outlines was updated to add support for a new stacked MLC
- Compatibility with SmartIMRT in Eclipse
- Addition of features previously available in ARIA Oncology Information Service; DICOM Worklist, Multi-Vendor DICOM Service, Queue, Varian Exchange.

Summary of Performance Data:

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.

Standards conformance: ARIA Radiation Therapy Management conforms in whole or in part with the following standards
IEC 61217:2011-12
IEC 62366: 2007/(R)2013
IEC 62366-2:2015
IEC 62304:2006
DICOM

Clinical Tests No clinical tests have been included in this pre-market submission.

Conclusions
The non-clinical data support the safety of the device and the software verification and validation demonstrate that the device performs as intended. Varian therefore considers ARIA Radiation Therapy Management 15.5 MR1 to be safe and effective and to perform at least as well as the predicate device.