APR 0 4 2014 K133572

Page 1 of 2

Premarket Notification [510(k)] Summary
ARIA Radiation Therapy Management

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

Submitter's Name:

Varian Medical Systems, Inc.
3120 Hansen Way C-260
Palo Alto, CA 94304

Contact Name: Peter J. Coronado
Phone: 650.424.5731
Fax: 650.842.5040
Date: November 2013

Trade Name: ARIA Radiation Therapy Management

Common Name: ARIA Radiation Therapy Management

Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: IYE

Predicate Device: ARIA Radiation Oncology: K093527

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.

- Device name change
- Removal of the MIRS features
- Re-structure and re-naming single software device feature into five features
- Improved rigid registration for patient position and n-point matching
- Third party compatibility
- Improved DICOM user interface
- Improved Off-Line Review detection and match
- Enhanced Portal Dosimetry gamma evaluation
- Improved workflow usability

Summary of performance testing: Results of verification and validation testing showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Standards conformance: ARIA Radiation Therapy Management conforms in whole or in part with the following standards:

IEC 61217:2008 IEC 62366:2007 IEC 62304 1st Ed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2014

Varian Medical Systems, Inc.
% Mr. Peter Coronado
Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K133572
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: February 28, 2014
Received: March 12, 2014

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133572

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

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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