DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 26, 2015

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

Re: K151882
Trade/Device Name: Varian Treatment (VTx)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 22, 2015
Received: September 25, 2015

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151882

Device Name
Varian Treatment (VT*x*)

Indications for Use *(Describe)*
Varian Treatment is designed to assist the operator of a radiation therapy device by retrieving treatment plans from the Varian System Database for ARIA® Radiation Therapy Management, by providing accurate treatment setups, by monitoring setup parameters, by preventing treatment when machine parameters are out of conformance to treatment plan parameters, and by sending the treatment history for recording to the Varian System Database.

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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510k Summary

510k Submission for Varian Treatment (VT*x*)

As required by 21 CFR 807.92, Reference: FDA's Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"(June 2014).

I. SUBMITTER

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E-110 Palo Alto CA 94304-1038
Contact Name:	Peter J. Coronado
Position:	Director, Regulatory Affairs
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Date Prepared:	Monday July 06, 2015

II. DEVICE

Name of Device:	Varian Treatment
Version:	Version 13.0
Common/Usual Name:	Accelerator, Linear, Medical
Regulation Name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Product Code:	IYE

III. PREDICATE DEVICE

Name of Predicate:	Varian Treatment
Version:	Version 6.6
510(k) Number:	K093967

IV. DEVICE DESCRIPTION

Varian Treatment (VT*x*) is a treatment delivery management application that performs an interface role between the ARIA® Oncology Information System for Radiation Oncology (ARIA OIS RO); ARIA® Radiation Therapy Management System (ARIA RTM), and an external radiation therapy delivery system (e.g., medical linear accelerator). The contents of this submission are applicable to version 13.0 of Varian Treatment.

The device does not contain any biologics or drug components. The device is not intended for single use. No parts of the system are provided sterile or are intended for sterilization. There are no patient-contacting materials. Varian Treatment is operated by radiation therapy therapists in accordance with the prescription of a radiation oncologist and under the general supervision of a chief therapist and medical physicist. Healthcare/treatment facilities are the intended environment of use.

The associated hardware for Varian Treatment consists of:

- Single workstation
- Two 27-inch monitors
- Mouse
- Keyboard
- In-Room Keypad
- MICAP
- KVM Switch
- Display Port Switcher
- Connecting Cables (Network, Serial, and Fiber)
- Barcode Reader (Optional Accessory)

The VT*x* workstation is the computer that hosts the system software described in this section. This workstation uses a mouse and keyboard for the operator's control in the treatment control room. Varian Treatment is connected over the institution's corporate network to the Varian system database via MICAP (firewall). Varian Treatment uses an in-room monitor and keypad to allow the operator certain functions from the treatment room. Barcode readers are connected to the VT*x* workstation for use with either PAVS or VVS when licensed (optional); these barcode readers are used for patient and accessory verification. The Display Port Switcher allows for switching between the In-Room monitor application and the Varian Treatment main application from the treatment room when PAVS or VVS is licensed. The KVM Switch and other Connecting Cables are used in connecting the in-room monitor to the VT*x* workstation.

The main software application for Varian Treatment provides functionality to load a patient session from the Varian System database, validates patient data, sends data to the treatment control system for the linear accelerator, verifies actual parameters versus planned parameters, receives treatment history and saves it to the Varian System database. VT*x* Administration is the administrative application for the main application, allowing a user to view, modify, and save configuration settings, user and group management, and group rights management for the VT*x* application. The Multivendor DICOM Service (MVDS) application acts between the main application and the external vendor's imaging system in supported, compatible devices. The VT*x* system software operates on a Microsoft® Windows® operating system on the workstation.

Additional details on the device features, design, and use were provided in the Device Description of this submission.

V. INDICATIONS FOR USE

Indications for Use Statement: Varian Treatment is designed to assist the operator of a radiation therapy device by retrieving treatment plans from the Varian System Database for ARIA® Radiation Therapy Management, by providing accurate treatment setups, by monitoring setup parameters, by preventing treatment when machine parameters are out of conformance to treatment plan parameters, and by sending the treatment history for recording to the Varian System Database.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are software that acts to interface between the ARIA® Oncology Information System for Radiation Oncology (ARIA OIS RO); ARIA® Radiation Therapy Management System (ARIA RTM), and an external radiation therapy delivery system (e.g., medical linear accelerator).

At a high level, the subject and predicate devices are based on the following same technological elements:

- Main software application - used to interface between designated systems
- Verification of accurately transferred parameter fields and information
- Prevention of treatment when machine parameters are out of conformance with treatment plan parameters
- Use of a barcode system (optional) to verify patient and treatment details
- Use with supported third-party medical linear accelerator devices
- Use with the Varian oncology information system (ARIA)
- Use of in-room components for operator access in treatment room

The following main differences exist between the subject and predicate devices:

- Compatibility with Windows® 7 x64, Embedded
- Support of QA Mode
- Support for additional treatment techniques available on certain compatible linacs
- Support of Varian Verification System (VVS)
- Added compatibility with Elekta Versa HD linac, Siemens ONCOR linac
- Added compatibility with ARIA 13.5 and 13.6
- Added Complete Irradiation Aperture Outline (CIAO) display feature

Further details about the differences between the predicate and subject device were included in the Substantial Equivalence Discussion of this submission.

VII. PERFORMANCE DATA

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

Non-Clinical Tests:

Biocompatibility Testing:

This item is not applicable to subject device; there are no patient-contacting components. No biocompatibility tests have been included in this submission in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC):

This item is not applicable to subject device; the device is software. No electrical safety and electromagnetic compatibility tests for the subject device, **Varian Treatment**, have been included in this submission in support of the substantial equivalence determination.

The computer workstation supplied by Varian is manufactured by a third-party representative and was tested against electrical safety and EMC requirements of the following standards: EN 55022 (*Class B*), EN 61000-3-2, EN 61000-3-3, EN 55024, & IEC 60950-1. The computer workstation that was provided with the predicate device met similar applicable electromagnetic compatibility and electrical safety requirements. As such, Varian believes that the computer workstation accessory hardware demonstrates equivalent performance with respect to EMC compatibility and electrical safety.

Software Verification and Validation Testing:

Software verification and validation testing were 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 a "major" level of concern as the device is an accessory to a device with "major" level of concern.

Verification and Validation testing was performed for all new software features and regression testing was performed against the existing features of Varian Treatment. System requirements created or affected by the device changes can be traced to the corresponding test results. The result of the software verification and validation testing was that the product conformed to the defined user needs, intended uses, and safety requirements.

Varian therefore considers the subject device software to be safe and effective and to perform at least as well as the predicate device software as demonstrated by the results from testing. There are no changes to the principle of operation of the software. The new software features are all considered by Varian to be enhancements of the predicate.

Mechanical and Acoustic Testing:

This item is not applicable to subject device; the device is software. No mechanical or acoustic tests have been included in this submission in support of the substantial equivalence determination.

Animal Study / Clinical Tests:

No animal studies or clinical tests have been included in this submission in support of the substantial equivalence determination.

VIII. CONCLUSIONS

The results of the non-clinical tests support the safety of the device and software verification and validation demonstrate that subject device, Varian Treatment Version 13.0, performs as intended in the specified use conditions. The non-clinical data also demonstrates that Varian Treatment version 13.0 is as safe and effective as and performs as well as or better than the predicate device, Varian Treatment version 6.6 (K093967).