K133331
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JAN 27 2014

4DITC 510(k) Summary as required by 21 CFR 807.92

Submitter's Name: Varian Medical Systems
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Director, Regulatory Affairs
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Date Prepared: October 28, 2013

Trade Name: 4D Integrated Treatment Console

Common Name: 4DITC

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

Predicate Device: Varian Medical Systems, Inc., 4D Integrated Treatment Console (k091132)

Device Description: The 4D Integrated Treatment Console (4DITC) allows the user to retrieve treatment plans and images from the Oncology Information System (IS) and send the plan and images to the Treatment Console System (TCS). The planned treatment parameters from the OIS are verified against the TCS delivery parameters for accuracy. All treatment parameters on the TCS must match the treatment parameters on the 4DITC before treatment can be delivered. After the treatment has been completed for the session, the user closes the session and treatment history is sent to the OIS to be recorded. The recorded treatment history can then be displayed and reviewed in the OIS.

The 4D Integrated Treatment Console has been modified to support additional treatment tasks and import/export interfaces. The following chart shows the new features as well as two features that have been removed in version 13.

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Technological Characteristics: Changes to the predicate devices are listed in the below table:

Features	**Predicate Device 4DITC (v8.8) K091132**	**Modified Device 4DITC (v 13)**
General description	The 4D Integrated Treatment Console (4DITC) is designed to allow treatment plans and images to be retrieved from the Oncology Information System (OIS) and sent to the Treatment Console System (TCS), planned treatment plan parameters to be verified against the TCS delivery parameters for accuracy and treatment history to be recorded in the OIS for use and display.	The 4D Integrated Treatment Console (4DITC) is designed to allow treatment plans and images to be retrieved from the Oncology Information System (OIS) and sent to the Treatment Console System (TCS), planned treatment plan parameters to be verified against the TCS delivery. parameters for accuracy and treatment history to be recorded in the OIS for use and display.
Indications for Use/Intended Use	The 4D Integrated Treatment Console is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring setup parameters and preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan	The 4D Integrated Treatment Console provides assistance for accurate treatment delivery by monitoring linear accelerator parameters and preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan
General Usage		
Imaging Only Sessions	No	Yes
Ad hoc kV imaging supported	No	Yes
Support the saving of Acquisition Module images in QA Mode	No	Yes
Conical Collimator support	Yes	Yes, Barcode Conical Collimator Verification (BCCV) and Integrated Conical collimator Verification & Interlock system (ICVI)
Bolus	Yes, Barcode verification	Yes, Barcode verification and Manual verification
Gantry angle acquired for treatment fields with adhoc CBCT fields	Yes	No
Support for Unplanned Treatments	No	Yes
Support for Flattening Filter Free treatments	No	Yes
Delta couch shift	No	Yes

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Features	Predicate Device 4DITC (v8.8) K091132	Modified Device 4DITC (v 13)
Enter in treatment notes and SSD's per plan/field	No	Yes
Support for multiple isocenters with grouping in a single plan	No	Yes
Major plan edits	Yes	No
High Intensity Mode (HIM) Also known as FFF (Flattening Filter Free)	No	Yes
UNIQUE Support	No	Yes
Varian Volumetric Modulated Arc Therapy (VVMAT vs. RapidArc support)	No	Yes
National Language Support (NLS)	No	Yes
Unicode Support	No	Yes
Stereotactic (SRS) – Dose Limit support for High Dose Technique	No	Yes
Integrated Conical Collimator Verification	No	Yes, Integrated Conical Collimator Verification and Interlock System (ICVI)

Note the reasons for the removal of features:

1. **Major Plan Edits:** We are no longer supporting major plan edits which were User Rights controlled outside of Unplanned Treatment Mode. This change will assure that edits to major plan parameters occur only in the Treatment Planning/Oncology Information Planning software or in the 4D Unplanned Treatment Mode.

2. **Gantry angle acquired for treatment fields with adhoc CBCT fields**: The intention of the feature was to allow the user to acquire the gantry angle on the adhoc CBCT field. The consequence was that the user could also acquire the new gantry angle for the treatment fields which is considered a major plan edit. Removing the capability to acquire the gantry angle for the treatment fields continues to allow the user to acquire the CBCT gantry angle, while honoring the Plan Edit Preferences in 4DITC Administration.

Verification and Validation Testing
Verification testing was performed to demonstrate that the performance and functionality of the new and existing features met the design input requirements.

Regression testing was performed to verify the integrity of any changes.

Validation testing was performed on a production equivalent device, under clinically representative conditions by qualified personnel.

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Verification &Validation Summary Report

Results from Verification and Validation testing demonstrate that the product met defined user needs and defined design input requirements. Varian, therefore, considers 4DITC to be safe and effective and to perform at least as well as the predicate device.

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

January 27, 2014

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

Re: K133331
Trade/Device Name: 4d Integrated Treatment Console
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: October 28, 2013
Received: October 29, 2013

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" (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 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

Indications for Use

510(k) Number (if known): K133331

Device Name: 4D Integrated Treatment Console (4DITC)

Indications For Use:

The 4D Integrated Treatment Console provides assistance for accurate treatment delivery for each patient by monitoring linear accelerator parameters and by preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) _____K133331_____