K091132

# Premarket Notification [510(k)] Summary
## 4D Integrated Treatment Console

JUN 17 2009

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

**Submitter's Name:**

Varian Medical Systems, Inc.
3100 Hansen Way e-110
Palo Alto, CA 94304

Contact Name: Vy Tran
Phone: 650/424.5731
Fax: 650/842.5040
Date: 16 April 2009

**Proprietary Name:**

4D Integrated Treatment Console

**Classification Name:**

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

**Common/Usual Name:**

4DITC

**Predicate Devices:**

4D Integrated Treatment Console, K050479
4D Integrated Treatment Console with PAVS, K081036

**Device Description:**

The 4D Integrated Console provides the user with:

- A treatment verification function – to assist the operator of a radiation therapy device in providing accurate treatment set-ups for each patient by monitoring set-up parameters
- Treatment safety by preventing the radiation therapy device from commencing irradiation when a linear accelerator, MLC, or MV imager parameter is out of conformance with the treatment plan
- The ability to select patients from a queue provided by the schedule
- The ability to retrieve plans from an information system for the selected patient
- The ability to evaluate a selected treatment plan to determine whether redefined dose limits will be exceeded
- The ability to acquire and edit positional data from radiation therapy devices
- The ability to override specific treatment parameters based on individual user rights
- The ability to send treatment records to an information system
- The ability to interact with the user controls of the PortalVision, the multi-leaf collimator system, the Patient Accessory Verification System, and the treatment verification function at a single workstation

- Provides access to the following:
  - Linear Accelerator
  - On-Board Imager
  - Trilogy RapidArc

The 4D Integrated Treatment Console has been modified to include additional accessory support, treatment tasks and import/export interfaces. For details, refer to the documentation in this submission.

Statement of Indications for Use: The 4DITC function is designed to assist the operator of 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.

Technological Characteristics: Refer to the Substantial Equivalence Comparison Chart

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Vy Tran
Vice President, Corporate Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way M/S E-110
PALO ALTO CA 94304-1129

JUN 17 2009

Re: K091132
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: IYE, MUJ
Dated: May 26, 2009
Received: May 27, 2009

Dear Ms. Tran:

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 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; 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.

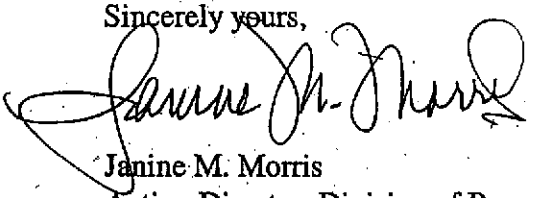
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology) | (240) 276-0120 |
| Other | | (240) 276-0100 |

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4D Integrated Treatment Console

# Indications for Use

510(k) Number (if known): K091132

Device Name: 4D Integrated Treatment Console

Indications for Use:

The 4DITC function 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 201 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091132