K093967

Premarket Notification 510(k) Summary

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way, E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: (650) 424-5731
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Date: December 2009

JUL 12 2010

Proprietary Name: Varian Treatment

Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5050, [redacted], MUJ

Common/Usual Name: Varian Treatment

Predicate Devices: Varian 4D Integrated Treatment Console, K050479

Device Description:

Varian Treatment is a software device that performs an interface role to the Siemens, GE, and Elekta linear accelerator systems. Varian Treatment (VT) allows treatment plans and reference images to be retrieved from the Varian System Database. VT sends the selected field of the loaded treatment plan down to the machine's treatment control software (TCS). VT verifies the field's planned parameters against the actual parameters of the TCS delivery system for accuracy before beam authorization is granted; this process is repeated for each field selected by the user. VT creates and transfers treatment records to the Varian System Database for storage.

Statement of Indications for Use:

Varian Treatment provides accurate treatment set-ups for each patient by monitoring linear accelerator set-up parameters and by preventing the radiation therapy device from commencing irradiation while any linear accelerator 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Vice President Corporate Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

JUL 12 2010

Re: K093967
Trade/Device Name: Varian Treatment
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 25, 2010
Received: May 27, 2010

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Varian Treatment (VTx)

Indications for Use

510(k) Number (if known): 093967

Device Name: Varian Treatment

Indications for Use:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093967