K111106

Premarket Notification [510(k)] Summary
TrueBeam Radiotherapy Treatment System

AUG 18 2011

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: June 2011

Proprietary Name: TrueBeam™

Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: 90 IYE

Common/Usual Name: TrueBeam Radiotherapy Delivery System

Predicate Device: Trilogy Mx Radiotherapy System and Accessories: K092871

Device Description: The TrueBeam™ Radiotherapy Delivery System is a medical linear accelerator that integrates the previously cleared Trilogy Radiotherapy system and associated accessories into a single device.

The system consists of two major components, a photon, electron, and diagnostic kV X-ray radiation beam-producing component that is installed in a radiation-shielded vault and a control console area located outside the treatment room.

Intended Use Statement The TrueBeam ™ system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Indications for Use Statement The TrueBeam ™ system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Technological Characteristics: Significant changes to the predicate device are listed below.

Feature	Cleared device	Device with change
Energy used	6-25MV	4-25MV
LaserGuard II	No	Yes
Proximity detection	Touchguards present on kV source, kV detector, positioning units	Addition of supplemental capacitive collision detection system (kV CCDS) on kV source

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

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

AUG 18 2011

Re: K111106
Trade/Device Name: TrueBeam Radiotherapy Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 7, 2011
Received: July 8, 2011

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

TrueBeam Radiotherapy Treatment System

Indications for Use

510(k) Number (if known): K111106

Device Name: TrueBeam Radiotherapy Treatment System

Indications for Use:

TrueBeam is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

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)

Mary S Patel

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

510K K111106