

K123291

DEC 20 2012

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

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: October 2012

**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:** TrueBeam Radiotherapy System and Accessories: K111106

**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                       | 4-25MV         | 2.5, 4-25MV        |
| 6 rotational Couch                | No             | Yes                |
| 2D/3D Matching                    | No             | Yes                |
| 4D CBCT                           | No             | Yes                |
| Multi-scan CBCT Acquisition       | No             | Yes                |
| Motion Management Interface (MMI) | No             | Yes                |

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



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

December 20, 2012

Ms. Vy Tran  
Vice President, Regulatory Affairs and Quality Assurance  
Varian Medical Systems, Inc.  
3100 Hansen Way, m/s C-255  
PALO ALTO, CA 94304-1038

Re: K123291

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: October 19, 2012  
Received: October 22, 2012

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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,

**Janine M. Morris -S**

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

# TrueBeam Radiotherapy Treatment System

## Indications for Use

510(k) Number (if known): K123291

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)



(Division Sign Off)  
Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123291

Page 1 of 1