



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

January 19, 2017

Re: K162472

Trade/Device Name: Truebeam, Truebeam STx, and Edge Radiotherapy Delivery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 22, 2016
Received: December 27, 2016

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 Industry and Consumer Education 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 Industry and Consumer Education 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,



FOR

Robert Ochs, Ph.D.
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)

K162472

Device Name

TrueBeam, TrueBeam STx and Edge Radiotherapy Delivery System

Indications for Use (Describe)

The TrueBeam and Edge Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

The TrueBeam and Edge Systems may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation and skull base tumors).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification [510(k)] Summary

TrueBeam Radiotherapy Treatment System

The following information follows the format of 21 CFR 807.92.

- I. Submitter's Name:** Varian Medical Systems, Inc.
3120 Hansen Way C-260
Palo Alto, CA 94304

Contact Name: Peter J. Coronado
Phone: 650.424.5731
Fax: 650.842.5040
Date: December 2016
- II. Trade Name:** TrueBeam™/TrueBeam STx™/Edge™
- Common Name:** Linear accelerator radiation therapy system
- Classification Name:** Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: 90 IYE
- III. Predicate Device:** TrueBeam Radiotherapy System and Accessories: K143224
- IV. Device Description:** The TrueBeam™ Radiotherapy Delivery System is a medical linear accelerator.
The system consists of two major components: 1) a photon, electron, and diagnostic kV X-ray radiation beam-producing component that is installed in a radiation-shielded vault in a healthcare facility and 2) a control console using the device software in an area located outside the treatment room.
- V. 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, TrueBeam STx and Edge Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

The TrueBeam and Edge Systems may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas,

lymphoid tumors (such as Hodgkin’s and non-Hodgkin’s lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation and skull base tumors).

VI. Technological Characteristics:

Listed below is a comparison of significant changes to the predicate device.

Feature	Cleared device	Device with change
Hyperarc Automated Dynamic Beam	No	Yes
Gated CBCT	No	Yes
Online 4D CBCT	No	Yes
Extended Length CBCT	No	Yes
iCBCT	No	Yes
4D CBCT reconstruction new algorithm	No	Yes
Automatic Exposure Control	No	Yes
Auxiliary Device Interface v3.0	No	Yes
Single Camera for Respiratory Gating	No	Yes

VII. Summary of performance testing:

Hardware and software verification and validation testing was conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards listed below. Bench testing results showed passing criteria were met, device conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Software verification and validation bench testing were conducted. Results showed passing criteria were met and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

The biocompatibility evaluation for the patient-contact materials in this medical device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on this medical device. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Standards conformance:

Varian TrueBeam™, TrueBeam STx™ and Edge™ medical linear accelerator models conform in whole or in part with the following FDA

recognized consensus standards:

AAMI/ANSI ES60601-1: 2005/ (R)2012 & A1:2012; C1:2009/ (R)2012 & A2:2010/ (R)2012 ANSI/AAMI/ISO 10993-1: 2009	IEC 60601-1-2:2007 IEC 60601-1-3: 2013 IEC 60601-1-6: 2013 IEC 60601-2-1: 2014 IEC 60825: 2007	IEC 61217: 2011 IEC 62274: 2005 IEC 62304: 2006 IEC 62366:2015 IEC 60976: 2007
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Conclusion: The results of verification, validation and safety standards bench testing demonstrate that the Varian Medical Systems TrueBeam™, TrueBeam STx™ and Edge™ medical linear accelerators are substantially equivalent to their predicate device.