



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

July 28, 2017

Re: K172013

Trade/Device Name: VitalBeam
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 30, 2017
Received: July 3, 2017

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,



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)

K172013

Device Name

VitalBeam

Indications for Use (Describe)

VitalBeam is 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.

VitalBeam 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.

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Premarket Notification [510(k)] Summary

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: July 2017

II. Trade Name: VitalBeam

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: K162472

IV. Device Description: VitalBeam is a medical linear accelerator.

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.

V. Intended Use Statement VitalBeam 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 VitalBeam 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:

Significant changes to the predicate device are listed below.

Feature	Cleared device	Device with change
Enlarged Bounding Box	No	Yes
Delta Couch shift	No	Yes
Single Isocenter Multiplan	No	Yes

Features cleared in TrueBeam™-TrueBeam STx™-Edge™ v2.7 (K162472) and included in VitalBeam v2.7:

- **Hyperarc™** – new automated treatment type
 - **Cone Beam Computed Tomography (CBCT) changes:**
 - **Gated CBCT** – New CBCT acquisition technique
 - **Online 4D & Extended Length CBCT** – New advanced reconstructor – imaging application integration
 - **iCBCT** – New CBCT images reconstruction algorithms
 - **4D CBCT Reconstruction** – New algorithms for binning CBCT projections into different phases within existing 4D CBCT feature.
 - **Automatic Exposure Control (AEC)** – New kV imaging system capability to control the kV exposure automatically
 - **Auxiliary Device Interface (ADI) 3.0** – New 3rd party device interface version
 - **Single Camera for Respiratory Gating** with new algorithms

VII. Summary of performance testing:

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

Software verification and validation testing were conducted and recorded as recommended by FDA’s “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. A failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

There was no change to the patient-contact materials biocompatibility in this medical device. Therefore, no change occurred in conformance to ANSI/AAMI/ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1”

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 VitalBeam™ medical linear accelerator model conforms 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 testing demonstrate that the VitalBeam medical linear accelerator is substantially equivalent to the predicate device.