Varian Medical Systems, Inc
℅ Lynn Allman
Senior Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO, CA 94304

December 21, 2023

Re: K232870
Trade/Device Name: TrueBeam, TrueBeam STx, EDGE and VitalBeam (4.1)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: September 15, 2023
Received: September 15, 2023

Dear Lynn Allman:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming

product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232870

Device Name

TrueBeam, TrueBeam STx, EDGE and VitalBeam (4.1)

Indications for Use *(Describe)*

TrueBeam-TrueBeam STx-Edge:

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 radiotherapy system can produce CBCT images that can be used in image guided radiation therapy, and the simulation and planning for adaptive radiation therapy.

The TrueBeam, TrueBeam STx 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 and skull base tumors), and medically refractory essential tremor (indicated for adults only).

VitalBeam:

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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Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

510(K) SUMMARY

The following information is provided as required by 21 CFR 807.92.

SUBMITTER	
Name and Address:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto, CA 94304
Contact Person:	Lynn Allman Sr. Director, Regulatory Affairs Phone: 650-424-5369 submissions.support@varian.com
Date Prepared:	15 September 2023

DEVICE	
Subject Device Name:	TrueBeam™ /TrueBeam STx™/Edge™/VitalBeam
Common/Usual Name:	Linear accelerator radiation therapy system
Product Code and Classification:	Medical charged-particle radiation therapy system IYE | 21 CFR 892.5050 | Class II

PREDICATE DEVICE	
Predicate Device Name:	TrueBeam™ /TrueBeam STx™/Edge™/VitalBeam (K231317)
Reference Device(s):	No reference devices were used in this submission.

DEVICE DESCRIPTION

The TrueBeam and VitalBeam Radiotherapy System is a medical linear accelerator that delivered therapeutic radiation to patient in accordance with the physician's prescription.

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

TrueBeam-TrueBeam STx-Edge: The TrueBeam ™ radiotherapy delivery system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

VitalBeam: The VitalBeam 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

TrueBeam-TrueBeam STx-Edge:

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 radiotherapy system can produce CBCT images that can be used in image guided radiation therapy, and the simulation and planning for adaptive radiation therapy.

The TrueBeam, TrueBeam STx, 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), and medically refractory essential tremor (indicated for adults only).

VitalBeam:

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).

The modification to the Indications for use do not change the Intended Use of the device, as the general purpose of the device and its function remain the same. There is no change to diseases or conditions the device is used for or the patient population for which the device is intended. Additionally, the intended therapeutic use of the device remains the same - "to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated." As demonstrated by the risk management activities per ISO 14971, the differences do not affect the safety and effectiveness of the device when used as labeled.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Both subject device and the predicate device contain the same technological characteristics and functional scientific technology to deliver radiation therapy and stereotactic radiosurgery by authorized medical practitioners. The Intended Use is unchanged. There are no changes in the principle of operation of the device. The biocompatibility of patient-contacting components remains the same as the predicate device. The results of the verification, validation and safety standards testing demonstrates that there are no changes to the safety profile of the device.

The modified device, referred to as the "subject device" throughout this summary, is release version v4.1 (version 4.1) of the TrueBeam-TrueBeam STx-Edge and VitalBeam System with additional software changes incorporated since the release version of the predicate device, version 4.0 (K231317).

At a high level, both the predicate device and the subject device are based on the same characteristics:

Both the subject device and the predicate device configurations use the same medical linear accelerator (linac) to deliver stereotactic radiosurgery and precision radiotherapy and support the same treatment techniques.

- Both devices use the same couch and support the same couch motions.
- Both devices use the same integrated treatment and imaging consoles and support external beam radiation delivery with X-RAY, Electron, and PHOTON beam for SRT/SRS.
- Both devices use the same muti-leaf collimators and support a range of imaging techniques.

The significant difference (based on "Deciding When to Submit a 510(k) for a Software Change to an Existing Device. (October 2017)") compared to the predicate device is: Version 4.1 incorporates changes to the CBCT image reconstruction algorithm to allow for the use of CBCT images in the simulation and planning for adaptive radiation therapy.

TrueBeam v4.1 cannot deliver adaptive dosimetry on a real-time, per-fraction basis, but does support off-line adaptive treatment planning or delivery.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Verification and validation of the capability of the modified software and hardware to produce CBCT images for Image Guided Radiotherapy and simulation and planning for adaptive radiation therapy was completed. The image quality and dose calculation accuracy was assessed and compared with planning CT images for its suitability to support adaptive planning.

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.

Test results showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Software verification and validation testing were conducted, 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.

There was no change to 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".

Human factors validation study was conducted according to the standard IEC 62366 to verify that TrueBeam, TrueBeam STx, Edge and VitalBeam v4.1 performs well as intended for the intended users, uses, and use environments.

The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

STANDARDS

Varian TrueBeam, TrueBeam STx, Edge and VitalBeam conforms to the following FDA recognized standards.

IEC 60601-1 Ed 3.1 and 3.2	IEC 62304:2006+A1:2015	ISO 10993-1:2018
IEC 60601-1-2:2014	IEC 62366-1:2015+A1:2020	ISO 15223-1:2021
IEC 60601-1-3:2008/A1:2013	IEC 61217:2011	ISO 13485:2016
IEC 60601-1-6:2010+A1:2013	IEC 60976:2007	ISO 14971:2019
IEC 60601-2-1:2020	IEC 62274:2005	ISO 20417:2021
IEC 60601-2-68:2014	AAMI RT2:2017	EN 1041:2018

CLINICAL TESTING

No animal or clinical tests are being submitted to establish substantial equivalence with the predicate device.

CONCLUSION

TrueBeam, TrueBeam STx, Edge and VitalBeam 4.1 is substantially equivalent to the TrueBeam, TrueBeam STx, Edge and VitalBeam 4.0 predicate device. The intended use is the same. The modifications to the indications for use do not change the Intended Use of the device, as the general purpose of the device and its function remain the same. The major technological characteristics are substantially equivalent to the predicate device, and the differences do not raise new questions of safety and effectiveness. The results of verification and validation as well as conformance to relevant safety standards demonstrate that TrueBeam, TrueBeam STx, Edge and VitalBeam meets the safety and performance criteria and is substantially equivalent to the predicate device.