Varian Medical Systems, Inc.
℅ Mr. Peter Coronado
Sr. Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

June 3, 2022

Re: K213977
Trade/Device Name: TrueBeam™, TrueBeam STx™, Edge™, VitalBeam
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: May 5, 2022
Received: May 6, 2022

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Julie Sullivan, Ph.D.
Assistant Director
DHT 8C: 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

Indications for Use

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

510(k) Number *(if known)*
K213977

Device Name
TrueBeam, TrueBeam STx, Edge,
VitalBeam

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, 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).

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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PREMARKET NOTIFICATION 510(k) Summary
TrueBeam and VitalBeam Radiotherapy Treatment System

K213977

The following information follows the format of 21 CFR 807.92

Submitter's Name:

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto CA94304

Primary Contact Person:

Peter J. Coronado
Sr. Director Regulatory Affairs
Phone: (650) 424.6320
Fax: (650) 646.9200
E-mail: submissions.support@varian.com

Date Prepared:

17 December 2021

Proprietary Name:

TrueBeam™ /TrueBeam STx™/Edge™/VitalBeam

Classification Name:

Medical charged-particle radiation therapy system

Regulation:

21CFR892.5050

Regulatory Class

Class II

Product Code:

IYE

Common/Usual Name:

Linear accelerator radiation therapy system

Predicate Devices:

TrueBeam Radiotherapy System and Accessories

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

The intended use is the same as the predicate.

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, 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).

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).

Significant Changes:

The **significant changes** in the subject device compared with the predicate device are:

- Operating System update from Windows 7 to Windows 10
- Isocentric Parameterization
- Unplanned treatment mode
- Imaging only session
- iCBCT Improvements (Improvements were made to both reconstruction algorithm and hardware accelerator. Notably a modified version of the McKinnon-Bates algorithm for improved 4D CBCT)

Summary 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. A subset of technological characteristics and features of the current device is different to the predicate. These differences are all enhancements of the predicate. The Intended Use and indications for use are 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 feature comparison chart below shows the difference between predicate and subject device. The features in **Blue text** in table below are new to the subject device.

Feature	**Predicate Device** **TrueBeam and VitalBeam v2.7** **(K171733 and K172013)**	**Subject Device** **TrueBeam-TrueBeamSTx-Edge and VitalBeam v3.0**
Intended Use: 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. 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.	Yes	Yes
Software Operating System	**Windows 7**	**Windows 10**
Treatment Techniques		

Feature	Predicate Device TrueBeam and VitalBeam v2.7 (K171733 and K172013)	Subject Device TrueBeam-TrueBeamSTx-Edge and VitalBeam v3.0
• Basic integral treatment techniques include static photon, static aperture photon arc, and dynamic conformal arc. • Additional treatment techniques include static electron and electron arc, IMRT/IMRS, RapidArc and VMAT, Total Body treatments (photon and electron). • All photon treatment delivery techniques can be delivered under respiratory gating conditions. • Fully automated treatment delivery	Yes	Yes
Unicode	Yes	Yes
Jaw tracking, Trajectory logs, RDSR & Smart connect	Yes	Yes
Automated Dynamic Beam (aka ADB /4Pi / Hyperarc)	Yes	Yes
Enlarged Bounding Box (w/in HyperArcTM)	Yes	Yes
Treatment Energy used 6-16 MV (BJR-17), 6-22 MeV	Yes	Yes
Treatment Energy used 4-25MV (BJR 17), 6-22 MeV	Yes	Yes
6x FFF (High Intensity Mode)	Yes	Yes
10x FFF (High Intensity Mode)	Yes	Yes
Varied Dose rate throughout arc travel - Dose rate RT: Up to 600 MU/min High dose rate: Up to 2400 MU/min	Yes	Yes
Varied gantry rotation speed throughout arc travel	Yes	Yes
Arc treatment Control points between two and 500; segments allowed with zero dose; allowed respiratory gating	Yes	Yes
Isocenter ≤1.5 mm for all three rotational axes	Yes	Yes
Single Isocenter Multiplan	Yes	Yes
LaserGuard II Gantry Collision Detection System	Yes	Yes
Couch		
Treatment Couch Motions		
• Small, corrective motions and large planned or targeted motions for couch longitudinal, lateral, vertical & rotational axes (4DoF). • Dynamic motion axes now include gantry, collimator (jaws,	Yes	Yes

Feature	Predicate Device TrueBeam and VitalBeam v2.7 (K171733 and K172013)	Subject Device TrueBeam-TrueBeamSTx-Edge and VitalBeam v3.0
MLC, collimator rotation), couch translation and rotation for patient set up and treatment delivery. • Local (in treatment room) couch motion control for manual positioning and automated positioning to plan values. • Tx Plans pre-treatment QA (incl. exceeding pre-defined dose limits)		
• Delta Couch automated patient alignment shifts (Delta Couch Shift). • (Varian Treatment Couch) – Linear Encoder	Yes	Yes
Qfix kVue One Couch Top: s/w support only + MPC support	Yes	Yes
Perfect Pitch – automated corrective motion for pitch and roll axes (6 degrees of freedom)	Yes	Yes
Treatment application recognizes common isocenter within and across plans then applies couch corrections to the common isocenter.	Yes	Yes
Integrated Treatment and Imaging Console		
External beam: X-ray & ELECTRON plus PHOTON beam for SRS/SRT delivery	Yes	Yes
Electron Energies: 7MeV & 11MeV	Yes	Yes
Coplanar, Non-coplanar, Arc fields	Yes	Yes
Beam shaping f(x): Dynamic wedges, Asymmetric collimators	Yes	Yes
Conical Collimator Verification (Varian ICVI)	Yes	Yes
Recognized patient-specific accessories: Electron Beam Collimators, Poured Blocks, Compensators, Physical wedges	Yes	Yes
Patient ID (bar code label) verification & Custom accessory verification (VVS compatibility) • Patient selection from queue provided by the schedule • Selected patient plan retrieval from info system • Electronically send Plan setup data to linac	Yes	Yes
VVS – CV (Varian Verification System, conical Cone Verification) compatibility	Yes	Yes
Set up verification & beam prevention if setup does not match Tx plan	Yes	Yes
Manual bolus verification	Yes	Yes
Override treatment parameters based on user rights and permit current session delivery only	Yes	Yes

Feature	Predicate Device TrueBeam and VitalBeam v2.7 (K171733 and K172013)	Subject Device TrueBeam-TrueBeamSTx-Edge and VitalBeam v3.0
HET console electronically sends Plan setup data to the HET system supervisor	Yes	Yes
Access to MLC shape editing	Yes	Yes
Graphical display/editing of field parameters	Yes	Yes
Auto sequencing of fields for the selected patient	Yes	Yes
• Record treatment delivery results • Send History to InfoSys archive in patient record	Yes	Yes
Interfaces: • DICOM RT/3.0 data and image import/export capability; • ADI v2.0 and v3.0	Yes	Yes
ADI 3.0 (6DOF wit Brainlab Interoperability)	Yes	Yes
Motion Management Interface	Yes	Yes
Multi-leaf Collimator		
120-Leaf MLC Maximum field sizes for 120 MLC: Static field size: 40cm x 40cm. Static aperture field size: 30cm x 40cm IMRT field size: 34 cm x 40 cm	Yes	Yes
HD120 MLC Maximum field sizes for HD120 MLC: Static field size (MLC retracted): 40cm x 40 cm Static aperture field size: 30cm x 22cm IMRT field size: 34 cm x 22 cm	Yes	Yes
Imaging Techniques		
MV Photon Imager Component	Yes	Yes
Reference Image Feature (Structure, Field Edges, Digital graticule)	Yes	Yes
Portal Image Matching: (Matching Common Features, Match Field Edges Plot, Matched Structures and Field Edges, Related Images, Double Exposure, ROI, couch shift values, respiratory-gated image	Yes	Yes

Feature	Predicate Device TrueBeam and VitalBeam v2.7 (K171733 and K172013)	Subject Device TrueBeam-TrueBeamSTx-Edge and VitalBeam v3.0
acquisition, marker matching and portal dosimetry image acquisition.)		
Low X imaging energy for high contrast portal imaging	Yes	Yes
kV Photon Imager Component	Yes	Yes
Integrated Component: MV Imager w/photon imaging: 43 x 43 imager	Yes	Yes
Proximity detection: Touch guards on kV source, kV detector, positioning units with addition of supplemental capacitive collision detection system (kV CCDS) on kV source	Yes	Yes
Type of digital image produced:		
• Digital radiographs, fluoroscopic image frames, cone-beam CT image projections, respiratory-gated radiographs, respiration-synchronized fluoroscopic image frames	Yes	Yes
• Offline 4D CBCT image projections	Yes	Yes
• Offline Multi-scan CBCT images	Yes	Yes
• 2D-3D Match	Yes	Yes
• Gated CBCT • Online 4D CBCT and Extended CBCT • Short Arc CBCT	Yes	Yes
• Iterative CBCT (iCBCT) • Automatic Exposure Control (AEC)	Yes	Yes
• Iterative CBCT (iCBCT - includes pelvis large and image gently)	Yes	Yes
• **iCBCT improvements (Improvement to the iCBCT algorithm, for when the patient's outer contour is changing during a CT scan.)**	**No**	**Yes**
• Marker-less 4D CBCT binning	Yes	Yes
Movie Encoding Service	Yes	Yes
Basis of image comparison: Soft tissue, bony anatomy, fiducial markers, digital representation of treatment aperture	Yes	Yes

Feature	Predicate Device TrueBeam and VitalBeam v2.7 (K171733 and K172013)	Subject Device TrueBeam-TrueBeamSTx-Edge and VitalBeam v3.0
Image comparison techniques: 2D-2D and 3D-3D image matching under fully automatic conditions using mutual information, or semi-automatic matching conditions with use of both automated image and manual matching, or fully manual matching conditions **Image comparison with:** Soft tissue, bony anatomy, fiducial markers, digital representation of treatment aperture	Yes	Yes
Auto Beam hold Improvements	Yes	Yes
Marking Pixel Detection	Yes	Yes
Imaging only session (plan is only available for imaging) and unplanned treatment mode (emergency treatment upto 5 fractions)	**No**	**Yes**
Respiratory Gating		
Respiratory Gating Component	Yes	Yes
Single gating camera & visual coaching device (VCD)	Yes	Yes
MPC		
MPC Collimator Device Check	Yes	Yes
Machine Performance Check of ICVI (MPC)	Yes	Yes
Developer Mode		
Dual Energy kV Imaging (XI) (Developer mode research use)	Yes	Yes
Systems		
Isocentric Parameterization	**No**	**Yes**
Other		
4 Rack Unit Workstation inheriting 4 computers	Yes	Yes
Encoder Diagnostics	Yes	Yes
kV source arm drive train (gearbox) (s/w support only)	Yes	Yes

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.

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 since 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 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 v3.0 performs well as intended for the intended users, uses, and use environments.

Electrical safety and electromagnetic compatibility (EMC) testing were 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 conforms to the following FDA recognised standards. For full details refer to Summary of Use of Voluntary Consensus Standards document in Section 09 of this 510k submission.

IEC 60601-1:2005	IEC 6060-1-2: 2014	IEC 60601-1-3:2008/A1:2013
IEC EN 60601-1-6: 2010+ A1: 2013	IEC 60601-2-1: 2009/A1: 2014	IEC 61217: 2011
IEC 62304:2006 +A1:2015	IEC 62366-1: 2015	IEC 62274: 2005
IEC 60825-1 Ed. 2.0 2007	IEC 60976 Ed. 2.0 2007	ISO 10993-1:2009
IEC 60601-2-68:2014	ISO 15223-1:2016	EN ISO 13485:2016
IEC 60601-2-68:2014		

TrueBeam, TrueBeam STx, Edge and VitalBeam was designed and developed, including verification and validation testing, within an established Quality System compliant to:

EN ISO 13485:2016 EN ISO 14971:2012
21 CFR §820 – Quality System Regulation

Conclusion of Non-Clinical testing

The outcome was that the product conformed to the defined user needs and intended uses and that there were no DRs (discrepancy reports) remaining which had a priority of Safety Intolerable or Customer Intolerable. Therefore, the subject device is substantially equivalent to the predicate device.

Argument for Substantial Equivalence to the Predicate Device

TrueBeam, TrueBeam STx, Edge and VitalBeam v3.0 (subject device) are substantially equivalent to the TrueBeam and VitalBeam v2.7 (predicate device). A subset of technological characteristics and features of the current device is different to the predicate. These differences are all considered by Varian to be enhancements of the predicate. The Intended Use and indications for use are unchanged. There are no changes in the principle of operation of the device. The results of the verification, validation and safety standards testing demonstrates that there are no changes to the safety profile of the device. Therefore, the TrueBeam, TrueBeam STx, Edge and VitalBeam v3.0 (subject device) is substantially equivalent to the TrueBeam and VitalBeam v2.7 (predicate device).