April 12, 2024

LinaTech LLC
Jonathan Yao
President
1294 Kifer Road #705
Sunnyvale, California 94086

Re: K232489
Trade/Device Name: VenusX
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: March 12, 2024
Received: March 12, 2024

Dear Jonathan Yao:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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.

510(k) Number *(if known)*
K232489

Device Name
VenusX

Indications for Use *(Describe)*
The VenusX radiotherapy delivery system is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

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.

510(k) SUMMARY - K232489

As required by 21 CFR 807.92

I. SUBMITTER

Submitter's Name:	LinaTech 1294 Kifer Road #705 Sunnyvale, CA 94086, USA
Primary Contact Person:	Jonathan Yao Phone: (408) 733 2051 Fax: (408) 733 2045 E-mail: Jonathanyao@LinaTech.com
Date Prepared:	11 April 2024

II. DEVICE

Proprietary Name:	VenusX
Common/Usual Name:	Medical Linear Accelerator
Classification Name:	Medical charged-particle radiation therapy system
Regulation:	21 CFR §892.5050
Regulatory Class:	Class II
Product Code:	IYE

III. PREDICATE DEVICE

Predicate Devices:	Varian UNIQUE (K101751)
Reference Device:	Varian On Board Imaging (OBI) (K042720)

IV. DEVICE DESCRIPTION

Device Description:

The VenusX Radiotherapy System is a medical linear accelerator that delivers therapeutic radiation to patient in accordance with the physician's prescription. It supports CRT /IMRT Treatment Techniques (Mode).

The system consists of a photon therapeutic 6 MV X-ray radiation beam producing component with a photon 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 AND INDICATIONS FOR USE

Intended Use:	The intended use is the same with precision radiotherapy as the predicate device. VenusX does not support stereotactic radiosurgery. The VenusX radiotherapy delivery system is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Indications for Use:	The VenusX radiotherapy delivery system is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

VI. TECHNOLOGICAL CHARACTERISTICS

Summary Of Technological Characteristics:	Both the VenusX and the predicate device contain similar technological characteristics and functional scientific technology to deliver radiation therapy by authorized medical practitioners. A subset of technological characteristics and features of the current device is different from the predicate. The biocompatibility of patient-contacting components remains the same as the predicate device. The results of the verification, validation and safety standards testing demonstrate that there are no changes to the safety profile of the device. The feature comparison chart below notes the similarities and differences between predicate, reference, and subject device.

The feature comparison with predicate device:

Attribute/ Feature	Predicate Device Varian UNIQUE K101751	Subject Device LinaTech VenusX
Intended Use	The UNIQUE is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.	The VenusX radiotherapy delivery system is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Indications for Use	The UNIQUE is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.	The VenusX radiotherapy delivery system is intended to provide precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Photon Energy (MV) available	6	6x (FFF)
Dose Rates	100 - 600 cGy/min for FF mode	600、800、1000 cGy/min for FFF mode
SAD (cm)	100	90
Maximum standard treatment field size	40cmx40cm	40cmx40cm
Number of MLC leaves	120	101 leaves in each of two orthogonal layers
Maximum leaf over travel distance (cm)	14	Upper layer 20 Lower layer 14
Average leaf transmission (%)	≤ 2.0	≤ 0.05
Leaf end physical position accuracy (cm)	≤ ± 0.1	≤ ± 0.1

Attribute/ Feature	Predicate Device Varian UNIQUE K101751	Subject Device LinaTech VenusX
Maximum leaf speed (cm/sec) is greater than 2.5	Yes	Yes
Electron Treatment Mode	No	No
Non-arc photon treatment mode programmable MU maximum dose is larger than 1999 MU	Yes	Yes
Patient support surface: couch pedestal with carbon fiber couch top for improved MV imaging	Yes	Yes
Microwave Source is Magnetron	Yes	Yes
Interface for External System Gating	Yes	Yes
MV Detector size	30cm x 40cm	43cm x 43cm
MV Pixel	1024 x 768	2816×2816
Radiation dose for MV Image is less than 1MU	Yes	Yes
Image registration with planning image	Yes	Yes
Basis of image registration are for minimum of	soft tissue, bony anatomy, fiducial markers, digital representation of treatment apertures.	soft tissue, bony anatomy, fiducial markers, digital representation of treatment apertures.
Data Interface is using DICOM RT/3.0 data and with image	Yes	Yes

Attribute/ Feature	Predicate Device Varian UNIQUE K101751	Subject Device LinaTech VenusX
Record treatment delivery results	Yes	Yes
Treatment Techniques (Mode)	CRT, IMRT	CRT, IMRT
Compatible TPS and OIS for the VenusX and compare with predicate.	UNIQUE is compatible with a commercially available independent third-party Radiation Treatment Planning System (TPS), Such as Eclips TPS，and also to compatible with the ARIA Radiation Therapy Management System (FDA No.: K173838) (OIS).	VenusX is compatible with a commercially available independent third-party compatible with TiGRT TPS (FDA No.: K090893)（TPS） and also ARIA (FDA No.: K173838)（OIS） system.

The feature comparison with reference device:

Attribute / Feature	Reference Device Varian OBI K042720	Subject Device LinaTech VenusX
Intended Use	The Varian On-Board Imager device (OBI) is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.	The VenusX's Cone Beam CT Imager device (CBCT) is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.
kV imaging	Yes	Yes
Cone-beam CT image Reconstruction	Yes	Yes
General type of Reconstruction method/algorithm	FDK (Feldkamp-Davis-Kress) algorithm	FDK (Feldkamp-Davis-Kress) algorithm
Dose per CBCT acquisition	≤ 1.4cGy	≤ 2cGy
CBCT acquisition mode (pixels / degrees)	512×512 reconstruction matrix / 200°（head） or 360°（body）	512×512 reconstruction matrix / 360°

VII. SUMMARY OF PERFORMANCE TESTING

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) testing was conducted on the subject device. The system complies with the following standards:

- IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Bench Test

The VenusX was thoroughly tested on bench to evaluate and verify that it meets the required performance specifications. The bench testing plan was developed based on the risk assessment of the device, and the recommendations outlined in the applicable FDA guidance documents, ISO and IEC standards. VenusX conforms to the following standards:

- ANSI AAMIES/IEC60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-1:2020 Medical electrical equipment - Part 2-1: Requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
- IEC 60601-2-68:2014 Medical electrical equipment - Part 2-68: Requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
- IEC 62274:2005 Medical electrical equipment– Safety of radiotherapy record and verify systems
- IEC 62366-1:2015+AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60976:2007 Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
- IEC 61217:2011 Radiotherapy equipment - Coordinates, movements, and scales

Test results met all the pre-determined acceptance criteria.

Cybersecurity

In addition to the bench testing, the VenusX was also thoroughly tested to verify that its cybersecurity objectives are fully met, and security risk control measures are effective. Specifically, the following cybersecurity testing was conducted:

— Security requirement testing that demonstrates requirement was implemented correctly.

— Threat mitigation testing demonstrating effective risk control measures according to the threat modeling.

— A closed box testing of known vulnerability scanning by qualified external testers, with reference to Section 9.4 of "IEC 62443-4-1 Security for industrial automation and control systems Part 4-1: Secure product development lifecycle requirements ".

— Penetration testing by qualified external testers.

The results of the cybersecurity testing showed that VenusX meets the cybersecurity requirements under Section524B(b) of FD&C Act.

Hardware and Software Verification and Validation Testing

Hardware and software verification and validation process were 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.

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, "Content of Premarket Submissions for Device Software Functions," issued June 2023. The software for this device is considered as a "enhanced" level of concern.

Biocompatibility Testing

Biocompatibility testing was conducted on the Carbon fiber couch top in accordance with ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The Biocompatibility testing conducted for the VenusX included the following:

- ISO 10993-5 Cytotoxicity Test
- ISO 10993-10 Skin Sensitization Test
- ISO 10993-10 Skin Irritation Test

Test results met all the pre-determined acceptance criteria.

VIII. CONCLUSION OF NON-CLINICAL TESTING

The results of testing showed that VenusX conforms to the defined user needs and intended uses and that there were no software DRs (Discrepancy Reports) remaining which had a priority of Safety Intolerable or Customer Intolerable.

IX. CONCLUSION FOR SUBSTANTIAL EQUIVALENCE TO THE PREDICATE AND REFERENCE DEVICE

The VenusX is substantially equivalent to the UNIQUE (K101751) (predicate device). The intended use is the same with precision radiotherapy as the predicate device. VenusX does not support stereotactic radiosurgery. A subset of technological characteristics and features of the current device is different to the predicate. However, the Verification and Validation demonstrate that the device is as safe and effective as the predicate and reference device. Based on the comparison and analysis above, the VenusX (subject device) is substantially equivalent to the UNIQUE (K101751) (predicate device).