October 19, 2026

Linatech, LLC
% Jonathan Yao
CEO
1294 KIFER RD.,
#705,
SUNNYVALE, CA 94086

Re: K260510
Trade/Device Name: VenusCT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: SFV
Dated: September 10, 2026
Received: September 10, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260510

Device Name
VenusCT

Indications for Use *(Describe)*
VenusCT is a computed tomography X-ray imaging system using the cone-beam technology which acquires a sequence of images of the head, including ear, nose and throat (ENT), of the other areas of the human skull and neck with sections of upper cervical spine, of the spine sections, of upper extremities including shoulder, upper arm, forearm, hand, relative joints and of lower extremities including hip, upper leg, lower leg, midfoot, forefoot, relative joints, for use in diagnostic support.
The device carries out such operations by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of the volume and then displaying two- and three-dimensional images.
The device is managed and used by doctors, radiologists, and other legally qualified professionals.

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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510(k) #:

510(k) Summary

Prepared on: 2026-02-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	LINATECH, LLC
Applicant Address	1294 Kifer Road, # 705 Sunnyvale, CA 94086 Sunnyvale CA 94086 United States
Applicant Contact Telephone	(408) 733 2051
Applicant Contact	Jonathan Yao
Applicant Contact Email	Jonathanyao@LinaTech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VenusCT
Common Name	Computed tomography x-ray system
Classification Name	Computed tomography x-ray system
Regulation Number	892.1750
Product Code(s)	SFV

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220664	NewTom 7G	JAK

Device Description Summary

21 CFR 807.92(a)(4)

Venus CT is a computed tomography X-ray system using the cone-beam technology.
Venus CT composition and function:
CT scanner: It consists of an X-ray tube, high-voltage generator, flat-panel detector, CT gantry, high-voltage cables, and electrical cabinet. It utilizes the differences in X-ray absorption by tissues of different densities to obtain images of the inside of the human body.
Patient couch: The Couch is used to position the patient.
Laser Positioning System: The laser beam forms a clear positioning line in space, helping operators accurately place patient at the scanning center of the CT machine, ensuring the accuracy and reliability of the scan results.
Console: The console is used to operate the system and monitor the scan. The Operator console includes a computer, monitors and hand control box. The hand control box provides operators with a convenient interface, allowing them to remotely control various actions of the CT scanner and the patient couch through buttons and knobs, such as starting a scan or adjusting the bed height. The console is equipped with a large monitor to display real-time image information and device status during scanning. The computer includes a high-performance processor, memory card, graphic card and storage devices, providing powerful computing capabilities for running the control software ICC. The network card ensures rapid data transmission, allowing CT images to be quickly transferred from the CT scanner to the control room computer system for diagnosis. The ICC software is the core of the entire system, offering a wide range of functions, including scanning parameter settings, image reconstruction, image post-processing, and storage management. Through the control software, operators can flexibly adjust scanning parameters according to different examination needs to achieve optimal image quality.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

VenusCT is a computed tomography X-ray imaging system using the cone-beam technology which acquires a sequence of images of the head, including ear, nose and throat (ENT), of the other areas of the human skull and neck with sections of upper cervical spine, of the

spine sections, of upper extremities including shoulder, upper arm, forearm, hand, relative joints and of lower extremities including hip, upper leg, lower leg, midfoot, forefoot, relative joints, for use in diagnostic support.
The device carries out such operations by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of the volume and then displaying two- and three-dimensional images.
The device is managed and used by doctors, radiologists, and other legally qualified professionals.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Indications for use are same for both subject device and predicate device with the exception that dento-maxillofacial complex, teeth, mandible, jaw, TMJ indications are not included in the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

The following technological specification differences exist between the subject and predicate devices:

Scan time& Exposure Time: Difference exists because of different detector frame rate and imaging protocol and VenusCT can do longer Scan time and Exposure Time to ensure image quality.

Software: Software (ICC) of subject device shares same reconstruction algorithm which is FDK with Software (NNT) of predicate device. The ICC software testing has been conducted and it proves its effectiveness and safety.

Detector: Subject device has wider anode angle, larger active detector area and smaller pixel size which enable larger 3D FOV and more detailed images.

Electrical factors: The subject device has wider input voltage and higher X-ray tube power. The electrical safety and electromagnetic compatibility testing have been conducted and it proves safety and effectiveness of subject device complies with IEC 60601-1

Filtration: Difference exists regarding desired x-ray beam spectrum and optimization of low dose imagine, the testing has been conducted and proves effectiveness and safety of subject device.

Machinery factors: Subject device has higher weight, larger bore size and smaller footprint for operation. The human factor engineering validation testing has been done to prove the safety and effectiveness of VenusCT.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The image-quality bench testing that included MTF, NPS, CNR, uniformity, beam-hardening artifact, metal artifact, geometric accuracy, and CTDI evaluations demonstrated that the VenusCT meets its specified performance requirements. In addition, the Clinical Data Evaluation Report, conducted by American Board of Radiology (ABR) board-certified radiologists, demonstrated acceptable clinical image quality. The Human Factors Engineering Report supported the safe and effective operation of the device. Collectively, these performance data support that VenusCT is substantially equivalent to the predicate device.