DeepSight Technology, Inc.
David Surber
RA/QA Manager
2953 Bunker Hill Ln
SANTA CLARA, CA 95054

August 1, 2025

Re: K250381
Trade/Device Name: DeepSight NeedleVue LC1 Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: July 15, 2025
Received: July 15, 2025

Dear David Surber:

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.

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,

Paramita Sengupta -S

For

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250381

Device Name

DeepSight NeedleVue LC1 Ultrasound System

Indications for Use *(Describe)*

The DeepSight NeedleVue LC1 Ultrasound System is intended for use in Abdominal, Pediatric, Small Organ, Peripheral Vascular, Fetal, Urological, and Musculoskeletal Conventional and Superficial Imaging. This device is indicated for Prescription Use Only and by qualified healthcare professionals (HCPs). The DeepSight NeedleVue LC1 ultrasound system is intended to be used by qualified and trained physicians or sonographers with at least basic ultrasound knowledge. The operator must have read and understood the user manual. The DeepSight NeedleVue LC1 ultrasound system is intended to be used in medical practices and clinical environments including healthcare facilities, hospitals and clinics.

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.

K250381

510(k) Summary 21 CFR 807.92

Submitter:

DeepSight Technology, Inc.
2953 Bunker Hill Lane
Santa Clara, CA 95054

Company/Submission Contact:

David Surber
Tel: 1.415.225.9937
Email: dsurber@deepsight.com

Date Summary Prepared: February 10, 2025
Device Trade/Proprietary Name: DeepSight NeedleVue LC1 Ultrasound System

Classification name, Class II

Predicate Device: GE Healthcare Logiq E9 Ultrasound System **(K152309)**

Subject Device Description: The DeepSight NeedleVue LC1 Ultrasound System is a general-purpose diagnostic ultrasound system that is mounted on a movable cart and has a mobile console that provides digital acquisition, processing, and display capabilities. The subject device has three major functional blocks that are consistent across ultrasound systems including the predicate:

- A front end, which includes a single curved (a.k.a. convex) array transducer and analog signal processing functions. This transducer transmits acoustic energy into the body and receives the resulting reflections, and performs the signal processing functions on them required to produce an ultrasound image (e.g., analog to digital conversion, noise filtering);

- A back end, which includes a user interface, memory, and export via USB. The user interfaces include a computer keyboard, standard ultrasound parameter controls, an LCD touch screen, acoustic output display and an LCD image display. The touch screen is divided into a display area and a user interaction area, and allows for patient data entry, transmit voltage adjustment, transducer/preset selection, depth and focus adjustment, annotation, freeze, image and clip capture, and measurements.

- Power systems which generate, regulate and supply the required voltages to the system parts.

Subject Device Intended Use: The DeepSight NeedleVue LC1 Ultrasound System is intended for use in Abdominal, Pediatric, Small Organ, Peripheral Vascular, Fetal, Urological, and Musculoskeletal Conventional and Superficial Imaging. This device is indicated for Prescription Use Only and by qualified healthcare professionals (HCPs). The DeepSight NeedleVue LC1 Ultrasound System is intended to be used by qualified and trained physicians or sonographers with at least basic ultrasound knowledge. The operator must have read and understood the user manual. The DeepSight NeedleVue LC1 Ultrasound System is intended to be used in medical practices and clinical environments including healthcare facilities, hospitals and clinics.

Substantial Equivalence Comparison

	Subject Device: DeepSight NeedleVue LC1 Ultrasound System	**Predicate Device: GE LOGIQ E9 (K152309)**
Product Codes	IYO - Ultrasonic Pulsed Echo Imaging System ITX - Diagnostic Ultrasonic Transducer	IYO - Ultrasonic Pulsed Echo Imaging System ITX - Diagnostic Ultrasonic Transducer IYN - Ultrasonic Pulsed Doppler Imaging System
Classification Regulations	892.1560 - Ultrasonic Pulsed Echo Imaging System; biopsy needle guide kit 892.1570 - Diagnostic Ultrasound Transducer	892.1550 - Ultrasonic Pulsed Doppler Imaging System 892.1560 - Ultrasonic Pulsed Echo Imaging System 892.1570 - Diagnostic Ultrasound Transducer
General Intended Use	Ultrasound imaging and evaluation of adult and pediatric patients	Ultrasound imaging and evaluation of adult and pediatric patients
Indications for Use	The DeepSight NeedleVue LC1 Ultrasound System is intended for use in Abdominal, Pediatric, Small Organ, Peripheral Vascular, Fetal, Urological, and Musculoskeletal Conventional and Superficial Imaging. This device is indicated for Prescription Use Only and by qualified healthcare professionals (HCPs). The DeepSight NeedleVue LC1 Ultrasound System is intended to be used by qualified and trained physicians or sonographers with at least basic ultrasound knowledge. The operator must have read and understood the user manual. The DeepSight NeedleVue LC1 Ultrasound System is intended to be used in medical practices and clinical environments including	Intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic and vascular).

	Subject Device: DeepSight NeedleVue LC1 Ultrasound System	Predicate Device: GE LOGIQ E9 (K152309)
	healthcare facilities, hospitals and clinics.	
Number of transducers provided	1	34
Imaging Modes	Ultrasound B-Mode, including harmonic imaging. Operating Modes: 2D-mode; 2D-mode with Harmonics Imaging	Ultrasound B, M, Color M, Color & Power Doppler and various combinations: B/M B/PW, Color/Pwr/PW, Harmonic, Coded Pulse, Realtime 3D & Multi-place, Elastography Imaging, Sear wave elastography (SWE)
User	Qualified physicians and trained healthcare professionals in hospitals, clinics and other point of care locations	Qualified physicians
Contact Type	Body surface	Body surface, Cavitary (TV, TR, TE) and intraoperative
Transducer type	Curved array	Support for: Matrix Array, Convex Array, Linear Array, Micro Convex Array, Sector Phased Array, Volumes Probes
Power source	120 VAC	120 VAC
Beamforming	Beamforming on both the transmit and receive sides, and data undergoes imaging reconstruction and processing	Beamforming on both the transmit and receive sides, and data undergoes imaging reconstruction and processing
Controls and Display	Touchscreen divided into image display and user interaction area	Control panel with touch screen for user interaction and tilt/swivel LCD type image monitor
Screen mount	Movable cart	Movable cart

As shown in the comparison table, the predicate device, the Logiq E9 Ultrasound System (K152309) is indicated for use in a broader range of anatomical regions than the subject device. The predicate device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical) while the subject device for just a subset of these applications.

The subject device and the predicate device have the same intended use and substantially the same indications for use. More specifically, in both the subject and predicate devices, the ultrasound system is intended for general ultrasound evaluation by a qualified health care

professional. These differences do not affect the safety and effectiveness of the device when used as labeled.

Summary of comparison of technological characteristics

Like the predicate LOGIQ E9, the DeepSight NeedleVue LC1 Ultrasound System is a general-purpose diagnostic ultrasound system that is mounted on a movable cart and has a mobile console that provides digital acquisition, processing, and display capabilities. Moreover, the subject device includes the same three major functional blocks that are consistent across ultrasound systems including the predicate, the front end, back end and power systems. Although some differences exist between the two ultrasound systems, these differences are limited and do not raise different questions of safety or effectiveness, as they do not introduce any new functionalities or alter how the device is used in any meaningful way. The two systems are technologically equivalent in all material respects.

Performance Testing:
The bench testing conducted consisted of all applicable testing specified in FDA's guidance documents, *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (February 2023) and *Content of Premarket Submissions for Device Software Functions* (June 2023). In addition, compliance data was provided for the following recognized standards and FDA Guidance:

Software:

- IEC 62304 Ed 1.1Consolidated Version Medical Device Software – Software Life Cycle Processes
- FDA guidance *Content of Premarket Submissions for Device Software Functions*
- FDA guidance: *Off-The-Shelf Software Use in Medical Devices*
- *FDA guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*

Ultrasound System and Transducer

Electromagnetic Compatibility	• IEC 60601-1-2 Ed. 4.1 Consolidated Version *Collateral Standard: Electromagnetic disturbances - Requirements and tests* • FDA guidance: *Electromagnetic Compatibility (EMC) of Medical Devices*
Thermal, Mechanical and Electrical Safety	• ES 60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2] *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* • IEC 60601-2-37 Edition 2.1, *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

Thermal and Mechanical Safety	• IEC 62359 Ed. 2.1 Consolidated Version, *Ultrasonics – Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields* • FDA guidance: *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*
Acoustic Output	• IEC 62127-1 Ed. 2.0, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields* • IEC 62127-2 Ed. 1.2 Consolidated Version, *Ultrasonics – Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz*
Acoustic Power	• FDA guidance: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers
Reprocessing	• FDA guidance: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers • FDA guidance: *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

Summary -Performance Testing (nonclinical)

The DeepSight NeedleVue LC1 Ultrasound System was found to have a safety and effectiveness profile that is similar to the predicate device based on the performance testing conducted of all applicable testing specified in FDA's guidance documents, *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (February 2023) and *Content of Premarket Submissions for Device Software Functions* (June 2023), along with compliance data provided for the following recognized standards and FDA Guidance.

Clinical Testing

Clinical data was not required for this submission.

Conclusion

The non-clinical (performance) data supports that the DeepSight NeedleVue LC1 Ultrasound System is as safe, as effective and performs as well as the predicate device. The hardware and software verification and validation demonstrate that the DeepSight NeedleVue LC1 Ultrasound System should perform as intended in the specified use conditions and demonstrates that the DeepSight NeedleVue LC1 Ultrasound System performs comparable to the predicate device that is currently marketed for the same intended use.