October 2, 2026

GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
Zahra Ghanian
Principal RA Specialist
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K261042
Trade/Device Name: Lung Guidance
Regulation Number: 21 CFR 892.2100
Regulation Name: Radiological acquisition and/or optimization guidance system
Regulatory Class: Class II
Product Code: QJU
Dated: September 1, 2026
Received: September 1, 2026

Dear Zahra Ghanian:

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,

MARJAN NABILI -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261042

Please provide the device trade name(s).

Lung Guidance

Please provide your Indications for Use below.

Lung Guidance software is intended to assist medical professionals in the acquisition of lung ultrasound images using image reference point(s) in the zones rather than the entire lung.

The Lung Guidance product is not intended to automatically capture, detect, or annotate all possible pathology that may be present(ed), and it is not intended to be the sole method to inform clinical decision making. The results of Lung Guidance along with the obtained lung ultrasound images, must be interpreted and reported by a qualified physician.

The Lung Guidance software utilizes the detection of landmarks in the lungs to guide the user in performing a standard 8-zone lung ultrasound protocol. The software is indicated for the acquisition of B-mode images of the following chest areas: upper anterior (R1, L1), lower anterior (R2, L2), upper lateral (R3, L3), and lower lateral (R4, L4).

The Lung Guidance software is indicated for use in patients older than 22 years of age where there is a clinical suspicion of a respiratory condition or disease and is intended to be an accessory to compatible ultrasound systems in environments where healthcare is provided.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary – Lung Guidance

GE HealthCare

Submitter

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC

3200 N Grandview Blvd.
Waukesha, WI, 53188, United States

Date Prepared: October 01, 2026

Contact Person: Zahra Ghanian

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Name of Device: Lung Guidance

Common or Usual Name: Lung Guidance

Classification Name: 892.2100 - Radiological acquisition and/or optimization guidance system

Regulatory Class: Class II

Product Code: QJU

Predicate and Reference Devices

	Predicate Device	Reference Device (for B-line functionality)
Manufacturer	Caption Health, Inc.	GE HealthCare
Device Trade Name	Caption Guidance	Venue
Submission number	DEN190040	K170714

A. DEVICE DESCRIPTION

Lung Guidance includes several product features intended to aid in the acquisition of lung ultrasound images: (1) static reference diagrams which assist the user with the initial positioning of the probe when beginning to scan and (2) deep learning algorithms to assist the user in capturing clips that are of diagnostic quality. The algorithm's features are described below in further detail:

- **Landmark Guidance:** This feature annotates lung landmarks in real-time, such as A-lines, pleural line, diaphragm, spleen/liver, as the user scans the lung.

- **Landmark Alignment Meter (Quality Meter):** This feature displays to the user in real-time how the movement of the probe gets closer or further away to the auto capture threshold and obtaining a diagnostic clip, as deemed by how aligned landmarks of interest are.
- **Landmark Autocapture:** This feature activates once the quality meter score is above the auto-capture threshold on the quality meter. Once the threshold is reached, the user is instructed to hold the probe steady while the image is being recorded.
- **Landmark Save Best Clip (SBC):** This feature may be used if the auto-capture threshold has not been met and the user wishes to use the highest quality clip that has been seen while scanning. A retroactive 3 second clip will be saved for that zone. The button displays a quality "score," which indicates how close the best clip is to the diagnostic-quality threshold.
- **B-line Annotation and Autocapture:** This feature activates for B-line pathology identified/annotated within each lung scanning zone and auto-captures B-lines that are seen while scanning.

In addition to automated clip acquisition features (Landmark Autocapture, Save Best Clip, and B-Line Autocapture), Lung Guidance provides a manual override option that allows the user to independently capture a clip of their choice. At any time during scanning, the expert user may manually record a clip by selecting the manual record (Video) button, which captures a retrospective clip without reliance on automated quality thresholds or device-determined probe positioning. This manual recording capability serves as an additional safety mechanism to ensure image acquisition in situations where automated capture criteria are not met and save-best-clip functionality is not utilized.

B. INTENDED USE / INDICATIONS FOR USE

Lung Guidance software is intended to assist medical professionals in the acquisition of lung ultrasound images using image reference point(s) in the zones rather than the entire lung.

The Lung Guidance product is not intended to automatically capture, detect, or annotate all possible pathology that may be present(ed), and it is not intended to be the sole method to inform clinical decision making. The results of Lung Guidance along with the obtained lung ultrasound images, must be interpreted and reported by a qualified physician.

The Lung Guidance software utilizes the detection of landmarks in the lungs to guide the user in performing a standard 8-zone lung ultrasound protocol. The software is indicated for the acquisition of B-mode images of the following chest areas: upper anterior (R1, L1), lower anterior (R2, L2), upper lateral (R3, L3), and lower lateral (R4, L4).

The Lung Guidance software is indicated for use in patients older than 22 years of age where there is a clinical suspicion of a respiratory condition or disease and is intended to be an accessory to compatible ultrasound systems in environments where healthcare is provided.

C. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Lung Guidance has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared Caption Guidance device, also manufactured by Caption Health (a GE HealthCare acquired company). A reference device for the B-line functionality included in the subject device is also provided (Venue, K170714) – manufactured by GE HealthCare. A substantial equivalence chart comparing the similarities and differences between the Lung Guidance, Caption Guidance, and Venue is provided as Table 1 below in this section. The minor differences in technological characteristics do not raise different questions of safety or efficacy. Software verification, validation and performance data demonstrate that the Lung Guidance is substantially equivalent to its predicate device.

Both Lung Guidance and Caption Guidance devices employ similar technological characteristics and principles of operation. Both devices are software-as-a-medical device products which utilize deep learning methods to provide real-time feedback/guidance to the operator for radiological acquisition of images. Both devices employ the use of a quality meter that moves according to how close or far away the user is from acquiring a diagnostic image of the lung or heart. Both devices include a Save-Best-Clip feature which is made available to user when autocapture cannot be obtained. The Save-Best-Clip feature operates in the same manner, where the highest-quality retroactive clip is saved for that view/zone. Furthermore, both Save-Best-Clip features display a quality “score,” which indicates how close the best clip is to the diagnostic-quality threshold. Both devices operate with compatible ultrasound systems, and all these technological features are intended to work in tandem to allow non-expert users to acquire diagnostic quality B-mode images.

Table 1: Substantial Equivalence Comparison Chart

	Subject Device	**Predicate Device**	**Reference Device (for B-line functionality in subject device)**	**Discussion**
Manufacturer	GE HealthCare	Caption Health (acquired by GE HealthCare)	GE HealthCare	Identical
Device	Lung Guidance	Caption Guidance	Venue	Not applicable
Submission number	K261042	DEN190040	K170714	Not applicable
Intended Use/Indications for Use	**Intended Use:** Lung Guidance software is intended to assist medical professionals in the acquisition of lung ultrasound images using image reference point(s) in the zones rather than the entire lung. The Lung Guidance product is not intended to automatically capture, detect, or annotate all possible pathology that may be present(ed), and it is not intended to be the sole method to inform clinical decision making. The results of Lung	The Caption Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. Caption Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems. Caption Guidance software is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients,	The Venue is a general-purpose diagnostic ultrasound system for use by qualified healthcare professionals. The clinical environments where the Venue can be used include critical care and emergency room environments, as well as point-of- care areas in offices, clinical and hospital settings for diagnosis of patients. The Venue is intended for ultrasound imaging,	Similar. The subject and predicate devices are intended to enable non-experts without prior ultrasonography experience to perform ultrasound scans in similar areas of the body (chest area) via structured protocols and both devices are intended to be used by the reading physician as part of patient evaluation (i.e., obtained images must be formally interpreted and reported by a qualified physician). The subject

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
	Guidance along with the obtained lung ultrasound images, must be interpreted and reported by a qualified physician. **Indications for Use:** The Lung Guidance software utilizes the detection of landmarks in the lungs to guide the user in performing a standard 8-zone lung ultrasound protocol. The software is indicated for the acquisition of B-mode images of the following chest areas: upper anterior (R1, L1), lower anterior (R2, L2), upper lateral (R3, L3), and lower lateral (R4, L4).	specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).	measurement and analysis of the human body and fluid for multiple clinical applications including: abdominal (GYN and Urology), thoracic/pleural, ophthalmic, Fetal/OB, Small Organ (including breast, testes, thyroid), Peripheral vascular, neonatal and adult cephalic, pediatric, musculoskeletal (conventional and superficial), cardiac (adults and pediatric), Transrectal, Transvaginal, and imaging guidance of interventional procedures (e.g. Nerve block, vascular access).	and predicate devices interface with compatible ultrasound systems for the acquisition of B-mode images, and the subject and references devices include a B-line feature which does not modify the primary intended use of ultrasound imaging. Lastly, both the subject and predicate devices are intended to be only used on adult populations.

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
	The Lung Guidance software is indicated for use in patients older than 22 years of age where there is a clinical suspicion of a respiratory condition or disease and is intended to be an accessory to compatible ultrasound systems in environments where healthcare is provided.		When Pinpoint GT Technology, from C.R. Bard, Inc., is included with the system, the Indications for Use include: Pinpoint GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.	
Classification Name	Image Acquisition And/ Or Optimization Guided By Artificial Intelligence	Image Acquisition And/ Or Optimization Guided By Artificial Intelligence	Ultrasonic pulsed doppler imaging system	Identical for the Subject and Predicate device
Product Code	QJU	QJU	IYN (Subsequent Codes: ITX, IYO)	Identical for the Subject and Predicate device
Modality	Ultrasound	Ultrasound	Ultrasound	Identical
Ultrasound System Compatibility	Vscan Air SL/CL	Terason uSmart 3200T	GE Venue	Substantially Equivalent: Both the predicate device and the subject device function as a software accessory to a

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
				cleared/marketed ultrasound device. Both ultrasound devices are cleared for the clinical application of acquiring ultrasound images.
Anatomical Site	Lung	Heart	Lung (B-lines)	Similar. Both devices image similar anatomical regions of the body. The ultrasound systems on which the subject and predicate devices operate on are cleared for ultrasound scanning in these anatomical areas.
Clinical Output/Protocol	8-zone protocol exam (ultrasound B-mode clips)	10-view cardiac exam (ultrasound B-mode clips)	Not applicable	Substantially equivalent. Both devices include structured protocols for the acquisition of a complete exam.
Device Users	Medical professionals	Medical professionals	Qualified and Trained healthcare professionals	Identical. Both devices are intended to enable non-expert health professionals without prior

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
				ultrasonography experience to perform ultrasound exams.
Labelled for Expert Physician Read	Yes	Yes	Yes	Identical. All exams must be reviewed by an expert reading physician.
Machine-Learning Based Algorithm	Yes	Yes	Yes	Substantially equivalent. Both devices utilize deep-learning artificial intelligence as the core technology to provide guidance/feedback to the user in order to optimize diagnostic quality images.
Real-time Guidance	Landmark-based	Prescriptive	Not applicable	Substantially equivalent. The predicate and subject devices incorporate real-time guidance features – in the predicate device, this guidance is provided prescriptively e.g., specific instructions on how to manipulate the transducer, whereas in the

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
				subject device, guidance is provided in the form of landmark annotations, where the user must match the landmark annotations to the reference image. Despite the differences in type of feedback/guidance, both the subject and predicate device are intended to aid the user in manipulating the transducer to the correct position to obtain a diagnostic quality image.
Auto-capture feature of diagnostic images	Yes	Yes	No	Identical. Both systems include automatic recording of clips which surpass predefined thresholds on the quality meter.
Meter feature	Yes (Landmark Alignment Meter)	Yes (Quality Meter)	No	Substantially equivalent. Both devices include a real-time quality bar

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
				providing feedback on the clip's quality, which visualizes to the user the expected diagnostic quality of the current image. This information can be used by the users to assess how close they are to capturing a diagnostic-quality image.
Save Best Clip feature	Yes	Yes	No	Identical. Both devices enable retroactive saving of the best quality clip seen during the scanning view, including displaying a landmark/quality "score," which indicates how close the best clip is to the diagnostic-quality threshold.
Overlay of B-lines	Overlay B-lines in a lung ultrasound scan in real-time.	No	Overlay B-lines in a lung ultrasound scan in real-time.	Identical. The subject and reference device both identify and annotate B-lines in real time. The type

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
				of annotation is similar in design, such that that the annotations do not obscure/hide the B-line artifacts visualized on the images
Scoring of B-lines	Producing a B-line count/number (1-10) of B-lines from lung ultrasound images which is mapped to a 3-bin category, score of (0-2)	No	Estimating count/number of B-lines from lung ultrasound images and producing a 3-bin category (0-2)	Substantially equivalent. The subject and reference device assign a numerical B-line score. The subject device relies on a percentage method to account for confluent B-lines whereas the reference device relies on a B-line counting mechanism. The difference in scoring approaches does not raise questions of safety as a greater number of B-lines (either via counting or percentage method) would be correlated with a

	Subject Device	Predicate Device	Reference Device (for B-line functionality in subject device)	Discussion
				greater B-line score. Standalone testing was performed to compare B-line scores from the Lung Guidance device to those from the ground truth from. Furthermore, all exams must be reviewed by an expert reading physician.
Predetermined Change Control Plan	No	Yes	No	

D. NONCLINICAL PERFORMANCE TESTING

Software V&V activities

Software documentation generated as part of GE HealthCare design process includes:

- Software Description
- Risk Management File
- Software Requirement Specifications
- Architecture Diagram(s)
- Software Design Specifications
- Traceability
- Software Development, Configuration Management, and Maintenance Practices Software Testing as Part of Verification and Validation Software Version History
- Unresolved Anomalies
- Cybersecurity documentation

A comprehensive risk analysis was generated for the software with detailed description of the hazards, their causes and severity, and acceptable methods for controlling them. GE HealthCare developed a description, with test protocols including pass/fail criteria and report of results, of acceptable verification and validation activities at the unit, integration, and system level.

Algorithm Performance Testing

Comprehensive non-clinical performance testing of the deep learning algorithms used in Lung Guidance was performed to further support the effectiveness of the device. Sampling from subjects included in the pivotal study were used to produce the datasets for the algorithm performance tests. The ground truthing for each feature was determined by the consensus among three experts in the field of lung ultrasound with the advanced level of expertise in lung ultrasound. Overall, the non-clinical performance testing results provide evidence in support of the functionality of Lung Guidance. The effectiveness of the subject device was assessed by taking into consideration the evidence from both bench testing and clinical testing.

The tests performed to assess the landmark guidance features (annotations, quality meter and Auto-capture/SBC functionality) and the B-line tool features (auto-capture, scoring, and annotation) are described in more detail below:

1. **Frame Level Landmark Guidance**

   The Lung Guidance product includes “landmark-based guidance” referring to detection and annotation of lung landmarks (such as A-lines, pleural line, rib shadows, diaphragm, abdomen (spleen, liver), and curtain sign) in real-time. Landmark detection/annotation is intended as guidance to the user on probe positioning, by annotating the presence and location of anatomical landmarks and artifacts during the clip acquisition only.

   The test was performed on 3078 frames from 20 patients’ ultrasound images). The mean PPV of 80.66% showed strong performance on overall classes. Moreover, the lower bound of the 95% CI for device performance on upper zones and lower zones exceeded the predetermined acceptance criteria.

2. **Relative Landmark Alignment**

   Quality Meter displays “reference landmark alignment score” to the user. This real-time feedback advises the user on the expected diagnostic quality of the resulting clip, such that the user can make decisions to further optimize the quality (alignment with the reference landmarks). Dynamically updating quality meter score and landmark features can be used to retrospectively capture the best two-to-four second image loop if auto-capture cannot be reached. This capture is done using the Save Best Clip (SBC) feature. SBC allows the user to save the highest image quality clip seen during scanning for the zone.

   For this study, the agreement was calculated between the device predictions on relative image quality, landmark alignment task and the ground truth. Both upper and lower zone groups achieved agreement significantly higher than the performance goal, meeting predetermined acceptance criteria. Across all 8 zones, overall agreement was 93.47% and significantly exceeded the pre-defined benchmark.

3. **Landmark Auto-capture Functionality**

   Auto-capture functionality emulates the way a sonographer knows when an image is of sufficient quality to be diagnostic and records it. The performance of the auto-capture feature was verified by comparing its decisions on whether to auto-capture clips against the ground truth, based on the decision of a panel of five human experts. The performance was measured by the area under the receiver operating characteristic curve (AUROC) and the positive predictive value (PPV). The mean AUROC and PPV were 91.10% and 91.07 exceeding the defined acceptance criteria across all 8 zones.

4. **B-line Auto-capture & Scoring**

Lung Guidance automatically detects B-lines in clips via the auto-capture feature. This feature monitors B-line scores continuously and automatically saves a recording of the detected B-lines if their score is above a threshold.

The performance of the B-line auto-capture feature was verified by comparing its decisions on auto-captured clips against the ground truth established by a panel of human experts. The auto-capture performance was measured by Balanced Accuracy (BA) and the positive predictive value (PPV). The mean Balanced Accuracy of 70.19% and PPV of 96.24% demonstrated that auto-capture performance exceeded the success criteria.

The performance of the B-line scoring function was assessed by Gwet's AC2 between the device prediction and the ground truth for B-line score evaluation. Gwet's AC2 of 97.06% with lower bound of 95% CI exceeded the performance goal. Moreover, the subgroup analysis results supported the generalizability of the device performance in B-line scoring across the confounding factors.

5. B-line Annotation

In addition to automatically detecting and scoring B-lines, the B-line tool also provides real time annotations of B-line structures. These annotations are not intended to diagnose B-lines but to guide image acquisition. This feature was verified by assessing the degree of overlap in localizing the position of B-lines using the Dice Similarity Coefficient (DSC) between the annotation from the Lung Guidance and the annotation from the Ground Truth. The results of this test demonstrated that the device performance of 58.88% exceeded the performance goals in B-line annotation task.

E. CLINICAL PERFORMANCE TESTING

Lung Guidance is designed as an assistive tool for trained sonographers/medical experts as well as medical professionals without specialized lung ultrasound (LUS) training.

A prospective multi-center pivotal clinical study was conducted to validate the performance of Lung Guidance in enabling trained healthcare professionals (THCPs) to perform an 8-zone lung ultrasound (LUS) exam to obtain diagnostic quality images and clips. THCPs in this Vscan Clinical study represented non expert medical professionals without specialized lung ultrasound training. The effect of Lung guidance on expert user performance was evaluated in a separate multicenter clinical study, which demonstrated that use of the device did not adversely affect expert user performance; rather, expert users benefited from use of the device.

1. Study Design

Lung Guidance was evaluated in a multicenter, prospective pivotal clinical study with 63 patients (per protocol[1] population), enrolled across two clinical sites in the United States and 14 users. Patients with known or suspected lung pathology and representative of the intended clinical population were consecutively enrolled to minimize selection bias, and written informed consent was obtained prior to any study procedures. The study was designed to assess whether Lung Guidance enables THCPs to acquire lung ultrasound examinations of sufficient diagnostic quality when compared with expert lung ultrasound (LUS) users.

Each participant was scanned twice using a standardized 8-zone protocol (R1–R4, L1–L4) with GE Vscan Air handheld ultrasound systems. Scans were performed using three probe configurations (curved, sector, and linear combinations), with the same probe type used for both THCP and expert scans within a subject to control for instrumentation effects. THCPs acquired images with Lung Guidance enabled (study exam), while expert users acquired control scans without Lung Guidance (control exam). Multiple clips could be captured per zone, with at least one clip per zone saved before advancing. Clips acquired with Lung Guidance were captured using autocapture or Save Best Clip, while expert clips were manually recorded. The THCP and expert scans were performed consecutively, with scanners blinded to each other's examinations.

Following image acquisition, all clips were reviewed by a panel of five independent expert lung ultrasound readers with a minimum of five years of LUS experience. Readers were blinded to user type (THCP vs expert), Lung Guidance usage, site, and other readers' assessments, and all landmark and B-line annotations were removed prior to review. Clips from all eight zones within a subject were presented together, while subject order was randomized. Readers independently assessed diagnostic image quality and the presence or absence of lung pathologies (including B-lines, pleural effusion, consolidation, and lung sliding). A majority vote across readers defined the ground truth for the primary endpoint, which was the proportion of patient studies with sufficient quality to support a clinical assessment, with secondary endpoints evaluating agreement in pathology detection between THCP-acquired and expert-acquired images.

[1] If a participant completed the study without any protocol deviations, withdrawals, adverse events, or incomplete data (for example, only having data from the THCP group and not the Expert group), then that participant was included as part of a Per-Protocol (PP) population for analysis. If any of the above events occurred, as long as the participant had complete data from the THCP group, then that participant was included as part of an Intention-to-Treat (ITT) population for analysis.

2. Primary Endpoint Results

The statistical analysis of the primary endpoint revealed a statistically significantly greater proportion of patient studies having an examination of sufficient diagnostic quality to make a clinical assessment than the established benchmark for the THCP group. 95.2% of THCP-acquired studies were rated as diagnostic quality, compared with 96.8% for expert-acquired studies. The between-group difference was −1.6 percentage points [95% CI: −18.7 to 15.5], further demonstrating comparable performance

between THCPs using Lung Guidance and expert users without Lung Guidance (i.e., Study exam Vs. Control exam).

In addition, a statistically significantly greater proportion of sufficient-quality studies was observed for aided THCPs at the zone-level except for the more challenging zone L4.

The following table summarizes the zone level performance of aided THCP users for Lung Guidance on Vscan Air system.

Parameter	Effective Sample Size	Estimate (%)
Overall (Patient-Level)	63	95.24
Zone L1	63	100.00
Zone L2	63	90.48
Zone L3	63	98.41
Zone L4	63	80.95
Zone R1	63	100.00
Zone R2	63	100.00
Zone R3	63	98.41
Zone R4	63	90.48

These results demonstrate that Lung Guidance enabled THCPs to consistently acquire lung ultrasound examinations of diagnostic quality at rates that exceeded the predefined acceptance criterion and were statistically comparable to expert performance.

The THCP group also performed favorably across all sub-groups for the primary endpoint: Age, BMI, Gender, Ethnicity, Site location and THCP profile. All point estimates were above the desired benchmark. In addition, the point estimates of the THCP group either matched or were slightly below the respective point estimates from the Expert group. Within each listed subgroup, the THCP group acquired high-quality studies to the level of being comparable to the Expert group.

3. Secondary Endpoint Results

Additional secondary endpoints were evaluated. The secondary endpoints provide descriptive clinical assessments, as no hypothesis testing was performed for the assessment of these endpoints. Five graders classified if a clip indicated a normal lung pathology, abnormal lung pathology, or if they were unable to determine whether there was pathology. The gradings were performed on both the THCP and Expert acquired clips, and the performances of the two groups were later compared.

Overall, Lung Pathology (Patient- and Zone-Level Agreement): As a secondary endpoint, agreement in overall lung pathology classification (normal vs. abnormal) between THCP-acquired exams using Lung Guidance and expert-acquired control exams was assessed using the scaled Gwet's Agreement Coefficient (AC1). At the patient level, agreement was 80.96%, exceeding the prespecified benchmark for strong agreement. At the zone level, agreement remained consistently high across all eight lung zones, with acceptable agreement, demonstrating robust concordance between aided and unaided acquisitions for overall pathology determination.

B-Lines Pathology: A performance assessment on the presence / absence of B-lines was also reported. Agreement in the detection of B-lines between THCP-acquired and expert-acquired images was evaluated at the zone level. Strong agreement was observed across all zones, with scaled Gwet's AC1 of 96.2% at the patient-level. The highest agreement was observed in anterior and upper lateral zones, while slightly lower, but still strong, agreement was noted in lower lateral zones, consistent with known challenges in imaging dependent lung regions. These results demonstrate reliable identification of B-lines in images acquired by THCPs using Lung Guidance.

Pleural Effusion: For pleural effusion detection, agreement between THCP and expert acquisitions was very high. At the patient level, scaled Gwet's AC1 was 94.02%. Zone-level agreement was similarly strong, with most zones demonstrating agreement values approaching or equal to 100%. These findings indicate excellent consistency between aided and unaided acquisitions for pleural effusion assessment.

Non-Aerated Lung / Consolidation: Agreement for non-aerated lung (NAL) or consolidation was also high across analyses. At the patient level, the scaled Gwet's AC1 was 95.67%. Zone-level agreement remained strong across all lung regions, generally exceeding 94%, indicating that THCP-acquired images using Lung Guidance supported reliable identification of consolidation patterns comparable to expert acquisitions.

Lung Sliding: Agreement in the assessment of lung sliding between THCP and expert exams demonstrated strong concordance. At the patient level, the scaled Gwet's AC1 was 95.57%. Zone-level agreement was uniformly high across all zones, with most zones demonstrating agreement values near 100%, reflecting the relative ease and robustness of lung sliding assessment across acquisition methods.

The results of the secondary analysis for the proportion of auto-captured clips and mean image acquisition time were calculated. The auto-capture rate was 51% across >1100 clips acquired by the THCP group. Across all patients, the mean acquisition time was 19.2 minutes (SD = 9.3 minutes). The auto-capture rate and mean acquisition time was consistent within the THCP group at both the patient level and zone level. However, lower lateral lung zones (Zone L4 and Zone R4) demonstrated a

lower auto-capture rate and longer mean acquisition time relative to other zones, consistent with increased acquisition complexity in dependent lung regions.

4. Objective Quantitative Results

Two analyses were performed on the Pivotal Study data to assess the performance of Lung Guidance using objective quantitative metrics:

B-line Count Results

An additional quantitative analysis of B-line count following similar approach used in the reference device (GE Venue K170714) was conducted and reported. At the zone level, the B-line count was measured as the maximum number of B-lines in each zone and at the patient level, the maximum number of B-lines across all zones is reported at the scale of 0-10. This assessment was performed to compare Bline counts in lung ultrasound clips acquired by THCPs using Lung Guidance with those acquired by unaided lung ultrasound experts, following an approach consistent with reference devices. Five blinded expert physicians independently assessed the maximum number of B-lines per zone and per patient using a standardized counting method, with inter-rater reliability evaluated at the patient level using Gwet's AC2 agreement coefficient. Gwet's AC2 agreement at both the patient level (91.45%) and zone level (greater than 95.05%) was strong.

This analysis, which supplements previously completed verification and clinical task-based assessments, demonstrates that Lung Guidance supports acquisition of lung ultrasound images suitable for quantitative B-line assessment and provides additional evidence supporting the safety and effectiveness of the device.

Pleural Line Thickness (PLT) Results

An additional quantitative analysis was conducted to evaluate the suitability of lung ultrasound images acquired with Lung Guidance for PLT measurement, consistent with the quantitative assessment approach used for the predicate device. Using DICOM-calibrated clips acquired with Lung Guidance integrated on the GE Vscan Air system, three blinded registered sonographers independently (1) assessed measurability and (2) performed PLT measurements in the six upper lung zones (R1–R3, L1–L3). Image suitability for PLT measurement was evaluated as the primary quantitative endpoint, with measurement variability reported descriptively as a secondary endpoint.

The results demonstrated that Lung Guidance supports acquisition of lung ultrasound images suitable for quantitative PLT assessment. Pleural line thickness (PLT) measurability met the predefined acceptance criterion of across all evaluated upper lung zones (L1–L3, R1–R3) for

images acquired by trained healthcare professionals (THCP) using Lung Guidance, with zone-level measurability comparable to expert-acquired images. Overall measurability exceeded 95% in most zones, and probe-specific analyses demonstrated acceptable performance across linear, curvilinear, and phased-array probes. Quantitative comparison of PLT measurements between THCP and expert arms showed strong concordance. Results indicated a small, proportional underestimation of PLT by the THCP arm, with a maximum underestimation of approximately 0.8 mm across zones. This level of bias was smaller than inter-operator variability among expert lung ultrasound users and considered clinically negligible. As THCP measurements preserved monotonic agreement with expert measurements and remained sufficient to identify clinically relevant pathology, supporting the conclusion that Lung Guidance enables acquisition of lung ultrasound images suitable for PLT measurement.

5. Human Factors Testing

Lung Guidance was evaluated for usability across a range of intended users, categorized into expert and non-expert groups. Expert user group included physicians and sonographers, and non-expert user group included registered nurses, and certified medical assistants. All users received the same amount of training, and all performed consistently across user groups.

Testing was conducted at the end of the device development process to assess user interactions with a user interface to identify use errors that could result in serious harm to the patient or user. No such errors were found – all users passed all critical tasks. The only use errors seen in non-critical tasks related to interpretation of the B-Line findings report, and accurate placement of the probe according to the positioning guidance. All users were able to successfully conduct an 8-zone LUS exam on a patient model. The usage of the Save Best Clip (SBC) feature in R4 (non-expert users) and L4 (both expert and non-expert users) demonstrated the utility of this feature in aiding image acquisition and reducing exam duration when autocapture is difficult to achieve.

An average of 93% of clips across zones were autocaptured across user types. Moreover, all zones except for L4 had an autocapture rate greater than 87%. Zone L4, which is known to be difficult to capture, was autocaptured at 77%; therefore, the relatively higher use of the SBC feature for this zone was expected. The results did not indicate significant differences in performance amongst user types, with expert users attaining an autocapture rate of 96%, and non-experts at 91.5%.

F. CONCLUSIONS

Lung Guidance is substantially equivalent to the predicate device, Caption Guidance. Both devices interface with compatible ultrasound systems for the acquisition of B-mode images and both devices are intended to be only used on adult populations. The subject device has the same general intended use and similar indications, technological characteristics, and principles of operations as the

previously cleared predicate device. Both devices are intended to enable non-experts without prior ultrasonography experience to perform ultrasound scans in similar areas of the body (chest area) via structured protocols, and the results of both devices along with acquired images must be formally interpreted and reported by a qualified physician. The minor differences in the indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled.

Both devices utilize deep-learning artificial intelligence as the core technology to provide feedback to the user to optimize diagnostic quality images via real-time guidance (landmark vs. prescriptive), similar diagnostic quality meter and image capture mechanisms (Auto-Capture and Save Best Clip). The minor differences in technological characteristics do not raise different questions of safety or efficacy. Performance data of software verification and validation as well as nonclinical and clinical performance testing have demonstrated that the Lung Guidance is substantially equivalent to its predicate device.