October 23, 2026

Deep Breathe, Inc.
Robert Arntfield
CEO and Founder
45 King St. #300
London, ON N6A1B8
Canada

Re: K261679
Trade/Device Name: BlineSlide
Regulation Number: 21 CFR 892.2060
Regulation Name: Radiological Computer-Assisted Diagnostic Software For Lesions Suspicious Of Cancer
Regulatory Class: Class II
Product Code: POK
Dated: September 17, 2026
Received: September 18, 2026

Dear Robert Arntfield:

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.

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,



Jessica Lamb, 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

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.	K261679

Please provide the device trade name(s).

BlineSlide

Please provide your Indications for Use below.

BlineSlide is intended for use as a concurrent reading aid to assist interpreting physicians, after lung ultrasound examinations of patients aged 18 years or older, by automatically identifying the absence of pleural line motion (lung sliding or lung pulse).

The device provides information on abnormal findings that may be useful in rendering potential diagnoses. Patient management decisions should not be made solely on the results of the BlineSlide's analysis.

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

K261679

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Submitter

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Date Prepared:	2026-04-17

Subject Device

Name of Device:	BlineSlide
Manufacturer:	Deep Breathe Inc.
Classification Name:	Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulation Number:	21 CFR 892.2060
Regulatory Class:	II
Product Code:	POK

Predicate Device

Name of Device:	Sonio Suspect
Premarket Notification:	K243614
Manufacturer:	Sonio
Classification Name:	Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulation Number:	21 CFR 892.2060
Regulatory Class:	II
Product Code:	POK

Reference Device

Name of Device:	BlineSlide
Premarket Notification:	K252007
Manufacturer:	Deep Breathe Inc.
Classification Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	QIH

Device Description

Device Overview

BlineSlide is a computer-aided diagnostic (CADx) cloud service application that assists qualified users with image-based assessment of lung ultrasound (LUS) cines acquired with the transducer placed perpendicular to the ribs, where the pleural line is the primary imaging target, from patients aged 18 years or older. It does not directly interface with ultrasound systems or receive data during the bedside examination.

BlineSlide takes as input user-uploaded de-identified B-Mode LUS cine loops (cines) in MP4 format and automatically identifies abnormal findings that may be useful in rendering potential diagnoses. Key features of the software are:

- **Pleural Line Motion Module:** an AI-assisted tool for detecting the absence of pleural line motion (lung sliding or lung pulse) in LUS cines

BlineSlide is incompatible with:

- Cines that are acquired from *Linear* array ultrasound transducers;
- Cines requiring more than 2048 megabytes of memory;
- Cines with a frame rate less than 18 frames per second;
- Cines that are less than 2600 milliseconds in duration;
- Cines that are greater than 7800 milliseconds in duration; and
- Cines in which the pleural line is not consistently within the field of view.

Each of these criteria are automatically assessed by the software. If detected, an output of *Cannot Evaluate* is returned to the user. A Cannot Evaluate output may occur even for technically adequate cines and does not necessarily indicate poor image quality. It neither indicates nor excludes the presence of pleural line motion. Guidance on how to proceed if a Cannot Evaluate output is returned is provided in the Instructions for Use.

BlineSlide does not perform any function that could not be accomplished by a trained user manually. It does not prescribe an acquisition protocol; cines should be acquired in accordance with standard clinical practice and applicable lung ultrasound guidelines. Patient management decisions should not be made solely on the results of BlineSlide's analysis.

Cines should be uploaded to BlineSlide as soon as practicable after acquisition and no later than 1 hour. Beyond this interval, including where connectivity does not permit upload, cines should be interpreted without device assistance. Care that is clinically indicated, including, but not limited to, intervention for suspected tension physiology, should not be withheld while awaiting a BlineSlide output.

Intended Patient Population

Patients aged 18 years or older.

Intended User

The intended user is a physician credentialed to use lung ultrasound clinically, such as internal medicine, emergency medicine, and critical care physicians.

Environment of Use

The environment of use includes any setting with reliable internet connectivity where lung ultrasound exams may be performed by credentialed physicians. This includes, but is not limited to, hospital-based environments such as intensive care units and emergency departments, and outpatient clinics.

Compatible Ultrasounds

De-identified cines imaged using non-linear array ultrasound transducers.

BlineSlide has been validated for use with cine loops acquired on the following ultrasound systems: Sonosite, Philips, Butterfly, Mindray, and GE. Performance has not been established for ultrasound systems not listed above.

Contraindications

None.

Indications for Use

BlineSlide is intended for use as a concurrent reading aid to assist interpreting physicians, after

lung ultrasound examinations of patients aged 18 years or older, by automatically identifying the absence of pleural line motion (lung sliding or lung pulse).

The device provides information on abnormal findings that may be useful in rendering potential diagnoses. Patient management decisions should not be made solely on the results of the BlineSlide's analysis.

Comparison of Technological Characteristics with the Predicate Device

The following table contains a comparison of the key technological features of the subject, predicate, and reference device:

Feature	**Subject Device** Blineslide	**Predicate Device** Sonio Suspect (K243614)	**Reference Device** BlineSlide (K252007)	**Discussion of Differences**
Intended Use	BlineSlide is intended for use as a concurrent reading aid to assist interpreting physicians, after lung ultrasound examinations of patients aged 18 years or older, by automatically identifying the absence of pleural line motion (lung sliding or lung pulse). The device provides information on abnormal findings that may be useful in rendering potential	Sonio Suspect is intended to assist interpreting physicians, during or after fetal ultrasound examinations, by automatically identifying and characterizing abnormal fetal ultrasound findings on detected views, using machine learning techniques. The device is intended for use as a concurrent reading aid on acquired images, during	BlineSlide is intended for noninvasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients aged 18 years or older with suspected disease.	Equivalent to predicate. Both devices are concurrent reading aids that automatically analyze ultrasound images and provide information to assist interpreting physicians. They differ in target population: The subject device indicated for patients aged 18 years or older having undergone a lung ultrasound examination. The predicate device is intended for adult pregnant female patients

	diagnoses. Patient management decisions should not be made solely on the results of the BlineSlide's analysis.	and/or after fetal ultrasound examinations. The device provides information on abnormal findings that may be useful in rendering potential diagnosis. Patient management decisions should not be made solely on the results of the Sonio Suspect analysis.		having undergone a fetal ultrasound examination. Performance testing results demonstrate that these differences do not raise new questions of safety nor effectiveness. Comparisons with the reference device are included because the subject device uses the same software system. All software architecture, infrastructure, and user interface components are identical; the only modification is the AI detection feature.
Image Modality	Lung ultrasound (LUS) video clips (cines)	Fetal ultrasound images	LUS cines	Equivalent to predicate. Both devices analyze standard diagnostic ultrasound data. Performance testing results demonstrate that the differences in anatomical application do not raise new questions of safety nor effectiveness.

				Identical to reference device.
Findings Detected	Absence or presence of pleural line motion artifacts	Absence or presence of abnormal fetal ultrasound findings	Absence or presence of B-lines artifacts	Equivalent. All devices automatically identify predefined ultrasound findings to assist physician interpretation. Performance testing results demonstrate that the differences in the specific findings detected do not raise new questions of safety nor effectiveness.
Algorithm Methodology	Computer vision Machine Learning-Based Algorithms	Computer vision Machine Learning-Based Algorithm	Computer vision Machine Learning-Based Algorithms	Identical.
Platform	Secure cloud-based web application compatible with uploaded ultrasound cines	Secure cloud-based and stand-alone software compatible with an ultrasound system	Secure cloud-based web application compatible with ultrasound cines	Equivalent to predicate. Both are cloud-based software devices that accept and analyze ultrasound inputs. Identical to reference. The devices use the same software system.
Report Creation	Yes. A table summarizing the device outputs for each uploaded cine is	No	Yes. A table summarizing the device outputs for each uploaded cine is	The subject device presents outputs in a structured summary table,

	displayed to the user.		displayed to the user.	while the predicate does not include the same reporting format. This reporting feature does not alter Intended Use or device function and does not introduce new risks. Identical to reference.

In summary, the subject and predicate devices share the same Intended Use: concurrent reading aids that assist interpreting physicians, after ultrasound examinations, by automatically identifying abnormal findings that may be useful in rendering potential diagnoses. In both cases, patient management decisions are not to be based solely on the device's analysis. Although the subject device is indicated following lung ultrasound in patients aged 18 years or older and the predicate device is indicated following fetal ultrasound examinations of adult pregnant female patients, both devices interpret ultrasound images using machine-learning based algorithms to detect predefined abnormalities.

Performance testing conducted in accordance with established validation protocols demonstrates that the subject device performs as intended within its intended patient population, and that the differences in target patient population do not raise new questions of safety or effectiveness. The addition of structured summary reporting into the subject device does not alter Intended Use or device function and does not introduce new risks.

Accordingly, the subject device, BlineSlide, is determined to be substantially equivalent to the predicate device, Sonio Suspect.

Performance Data

Summary of Non-Clinical Tests

Verification and Validation

The software was developed and evaluated in accordance with the FDA's Basic Documentation Level for software of low risk. Verification activities included unit, integration, and system-level testing, which demonstrated that all software requirements were correctly implemented and

performed as intended. Validation testing was conducted on a representative system configuration and confirmed the software's performance in relevant use conditions.

Risk Assessment

A risk analysis was conducted following the principles of ISO 14971 and applicable FDA guidance. The analysis identified potential hazards, assessed associated risks, and implemented risk control measures. All residual risks were evaluated and deemed acceptable based on the device's intended use and benefit-risk profile.

Cybersecurity Assessment

A comprehensive cybersecurity assessment was performed in accordance with FDA's premarket cybersecurity guidance and industry best practices. The device underwent penetration testing, vulnerability scanning, and a Common Vulnerabilities and Exposures (CVE) analysis. Identified threats were reviewed and mitigated using accepted controls, and no unmitigated high-severity vulnerabilities remained at the time of release.

Standalone Performance Assessment

The performance of the Pleural Line Motion Artifact Detection Module was successfully evaluated on a test dataset of 818 cines encompassing diverse demographic and imaging variables (**Table 1**). Cines were acquired from a variety of clinical sites in cities with diverse race and ethnicity populations.

Characteristic	Distribution
Age (years)	18 to 21 (3); 22 to 39 (30); 40 to 64 (116); Over 65 (182); Unknown (487)
Sex	Male (204); Female (120); Unknown (494)
BMI (kg/m^2)	Under 25 (49); 25 to 30 (40); Over 30 (57); Unknown (672)
Acquisition Region	Anterior (380); Anterolateral (72); Posterior (9); Unknown (357)
Manufacturer	Sonosite (572); Philips (135); Butterfly (60); GE (26); Mindray (24); Konica Minolta (1)
Transducer	Phased Array (656); Curved Linear (162)
Image Quality	Good (532); Poor (286)

Table 1. *Standalone Dataset Characteristics.*

The test data was entirely separated from that used for development. To ensure such data separation and generalizability, the data sources used in the test set were entirely different and geographically distinct from the data sources used in the development set.

Ground truth for the presence or absence of pleural line motion artifacts was determined by consensus agreement of two or more experts. In rare cases where consensus could not be reached due to poor image quality, clips were excluded from the performance assessment. In total, 36 clips met this criterion, representing only 4.2% of all cases considered. After exclusions, the final dataset comprised 202 positive class examples with Pleural Line Motion Artifacts Absent and 616 negative class examples with Pleural Line Motion Artifacts Present. Performance was assessed by measuring agreement using sensitivity and specificity as co-primary endpoints with Cannot Evaluate outputs scored as false predictions. The reliability of the module compared to reference data is summarized in **Table 2** below.

	Reliability
Sensitivity	0.94 (95% CI: 0.89 – 0.96)
Specificity	0.87 (95% CI: 0.84 – 0.89)

Table 2. *Blineslide's Reliability for Detecting the Absence of Pleural Line Motion Artifacts.*

Module performance was also assessed across a wide range of key cohorts, including imaging characteristics (ultrasound vendor, transducer type, image quality, acquisition region), demographic variables (sex, age, body mass index), and artifact patterns (lung pulse, lung point, lung sliding). The evaluation concluded that performance was consistent across clinically meaningful cohorts.

		Sensitivity		**Specificity**	
Cohort		**Sample Size**	**Estimate** *(95% CI)*	**Sample Size**	**Estimate** *(95% CI)*
Image Quality	Good	130	0.95 (0.89 – 0.97)	402	0.89 (0.85 – 0.92)
	Poor	72	0.92 (0.83 – 0.96)	214	0.84 (0.78 – 0.88)
Vendor	Sonosite	146	0.94 (0.89 – 0.97)	426	0.85 (0.82 – 0.88)
	Philips	47	0.96 (0.86 – 0.99)	88	0.85 (0.76 – 0.91)
	Butterfly	5	0.60 (0.23 – 0.88)	55	0.93 (0.83 – 0.97)
	Mindray	3	1.00 (0.44 – 1.00)	21	1.00 (0.85 – 1.00)
	GE	1	1.00 (0.21 – 1.00)	25	1.00 (0.87 – 1.00)

Transducer	Phased	144	0.92 (0.87 – 0.96)	512	0.88 (0.85 – 0.90)
	Curved Linear	58	0.97 (0.88 - 0.99)	104	0.83 (0.74 – 0.89)
Acquisition Region	Anterior	121	0.96 (0.91 – 0.98)	259	0.88 (0.84 – 0.92)
	Anterolateral	12	1.00 (0.76 – 1.00)	60	0.85 (0.74 – 0.92)
	Posterior	6	1.00 (0.61 – 1.00)	3	0.67 (0.21 - 0.94)

Table 3. BlineSlide's Standalone Performance Stratified Across Imaging Characteristics.

Summary of Clinical Tests

The diagnostic accuracy of readers aided by BlineSlide's Pleural Line Motion Module was successfully evaluated against unaided reader accuracy in a retrospective multiple reader multiple case (MRMC) study. The study dataset encompassed diverse patient demographics and image characteristics, was entirely separated from the development datasets by geography, and was not used for any part of the module's development. Readers were representative of the intended user population of the device across U.S. medical practice.

The evaluation dataset comprised 400 lung ultrasound cines (200 positive, 200 negative), sourced from multiple clinical sites (58.3% U.S.), spanning multiple ultrasound vendors, transducer types, image quality levels, and patient demographic variables. Complete demographic data was not available for all patients in this dataset, with BMI being unknown in 60% of cases, age in 65% of cases, and sex in 67% of cases. The chest region scanned (anterior, anterolateral, or posterior) was unknown in 48% of cases. Ground truth was determined by consensus of two or more clinical experts. Twenty-five readers completed the study, all holding U.S. Board Certification in Emergency Medicine, Internal Medicine, or Critical Care Medicine.

The primary endpoint was the difference in mean reader AUC between aided and unaided conditions. The predefined success criterion was met. Mean reader performance under aided and unaided conditions is summarized in Table 4 and average ROC curves are presented in Figure 1. No adverse effects or patient safety events were observed.

	AUC (95% CI)	**Sensitivity (95% CI)**	**Specificity (95% CI)**
Aided	0.922 (0.892 - 0.953)	0.880 (0.856 - 0.904)	0.841 (0.811 - 0.872)
Unaided	0.855 (0.807 - 0.902)	0.716 (0.690 - 0.742)	0.820 (0.798 - 0.842)

Difference	**0.068 (0.036 - 0.100)**	0.164 (0.142 - 0.187)	0.021 (-0.001 - 0.044)

Table 4. *Improvements in Reader Average Performance when Aided by BlineSlide.*

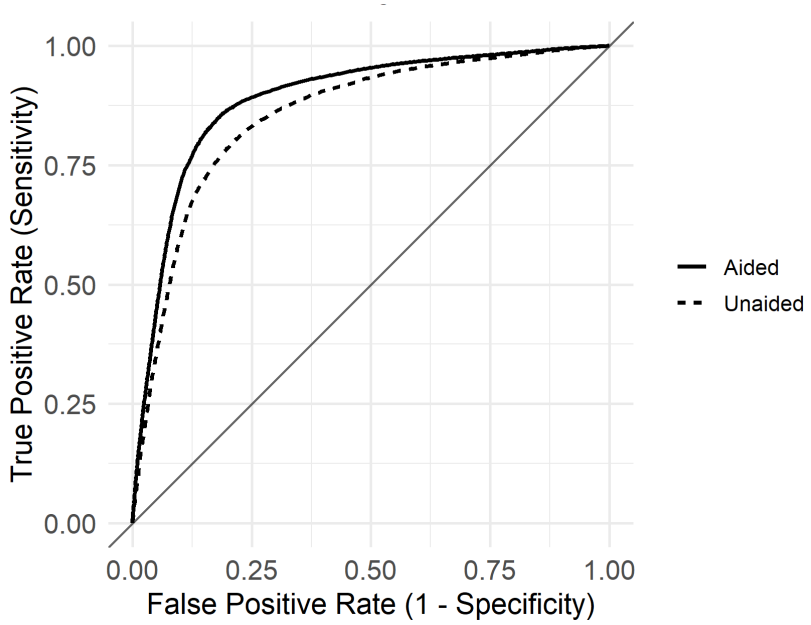


Figure 1. *Average Unaided (dashed) and Aided (solid) ROC Curves.*

The improvement in reader specificity, 0.021 (95% CI: −0.001 – 0.044), was not statistically significant. However, reader specificity was not a primary endpoint, and the benefit-risk profile of the device remains favourable: device assistance significantly improves overall accuracy, principally through the detection of absent pleural line motion (Table 4). Absent pleural line motion is the finding readers identified least accurately unaided, and the finding whose non-recognition carries the greater clinical consequence.

BlineSlide's effect on reader diagnostic accuracy was also evaluated across key patient, imaging, and reader-level cohorts.These analyses are not powered to detect statistically significant differences, and the results are not intended to statistically support performance claims for any individual cohort. Rather, they are intended to illustrate how aided performance varied across the intended patient population and user base and should not replace clinical judgment when interpreting device output for an individual patient. Aided performance across patient and imaging characteristics is summarized in Table 5, and across reader characteristics in Table 6.

Aided AUC, sensitivity, and specificity confidence intervals overlapped or exceeded the corresponding overall study confidence intervals in all evaluable cohorts (Table 4), indicating performance consistent with the overall study results. Aided AUC and sensitivity exceeded unaided metrics in all evaluable cohorts. Aided specificity exceeded unaided specificity in most

cohorts. The exceptions were patients aged 40 to 64 years (aided 0.79, unaided 0.82), patients with a BMI under 25 (0.85, 0.89) or over 30 (0.71, 0.78), female patients (0.81, 0.81), and emergency medicine physicians (0.88, 0.89). This is consistent with the overall study specificity finding described above and does not change the overall risk/benefit assessment for the device's intended use.

No estimate is reported where a cohort contained fewer than two cines of the relevant class: all metrics for patients aged 18 to 21 years (1 cine); AUC and specificity in the posterior acquisition region (1 negative class cine); and AUC and sensitivity for GE ultrasound systems (1 positive class cine).

Variable	Cohort	AUC	Sensitivity	Specificity
Age (years)	22 to 39	0.96 (0.93-0.99, 13)	0.93 (0.85-0.97, 6)	0.91 (0.82-0.96, 7)
	40 to 64	0.93 (0.88-0.98, 54)	0.90 (0.83-0.94, 39)	0.79 (0.64-0.89, 15)
	Over 65	0.95 (0.93-0.98, 72)	0.88 (0.83-0.92, 57)	0.92 (0.88-0.95, 15)
BMI (kg/m^2)	Under 25	0.92 (0.83-1.00, 24)	0.82 (0.69-0.90, 17)	0.85 (0.59-0.95, 7)
	25 to 30	0.96 (0.92-1.00, 15)	0.90 (0.82-0.94, 10)	0.96 (0.91-0.98, 5)
	Over 30	0.89 (0.74-1.00, 21)	0.87 (0.79-0.92, 16)	0.71 (0.38-0.91, 5)
Sex	Female	0.93 (0.89-0.98, 38)	0.92 (0.88-0.95, 22)	0.81 (0.67-0.90, 16)
	Male	0.94 (0.92-0.97, 95)	0.86 (0.81-0.90, 74)	0.90 (0.85-0.93, 21)
Acquisition Region	Anterior	0.94 (0.91-0.97, 168)	0.90 (0.87-0.92, 119)	0.85 (0.78-0.90, 49)
	Anterolateral	0.95 (0.91-0.99, 34)	0.93 (0.89-0.95, 12)	0.83 (0.73-0.90, 22)
	Posterior	Insufficient Data	0.95 (0.94-0.96, 6)	Insufficient Data
Ultrasound Vendor	Butterfly	0.94 (0.84-1.00, 29)	0.79 (0.48-0.94, 5)	0.94 (0.91-0.96, 24)
	GE	Insufficient Data	Insufficient Data	0.95 (0.92-0.97, 20)
	Mindray	0.96 (0.89-1.00, 18)	0.91 (0.74-0.97, 3)	0.91 (0.85-0.95, 15)

	Philips	0.93 (0.89-0.98, 86)	0.90 (0.85-0.94, 47)	0.83 (0.74-0.90, 39)
	Sonosite	0.90 (0.87-0.93, 245)	0.87 (0.84-0.90, 144)	0.79 (0.74-0.83, 101)
Transducer Type	Curved Linear	0.94 (0.90-0.98, 98)	0.92 (0.88-0.94, 58)	0.85 (0.77-0.90, 40)
	Phased Array	0.92 (0.88-0.95, 302)	0.87 (0.83-0.89, 142)	0.84 (0.80-0.87, 160)
Image Quality	Good	0.94 (0.90-0.97, 253)	0.90 (0.87-0.92, 129)	0.87 (0.82-0.90, 124)
	Poor	0.90 (0.86-0.94, 147)	0.85 (0.79-0.89, 71)	0.80 (0.74-0.85, 76)

Table 5. Average reader performance when aided by BlineSlide across patient and imaging characteristics. Metrics are reported as [point estimate (95% confidence interval, sample size)]. Analyses are not powered to detect statistically significant differences and are not intended to support performance claims for any individual cohort (see accompanying text).

Variable	Cohort	Readers	AUC	Sensitivity	Specificity
Specialty	Critical Care	9	0.93 (0.90 - 0.96)	0.90 (0.87 - 0.92)	0.84 (0.80 - 0.87)
	Emergency	7	0.94 (0.91 - 0.97)	0.89 (0.86 - 0.91)	0.88 (0.84 - 0.90)
	Internal	9	0.90 (0.82 - 0.98)	0.85 (0.82 - 0.88)	0.82 (0.78 - 0.85)
Experience	≤ 10 years	14	0.94 (0.92 - 0.96)	0.91 (0.88 - 0.93)	0.87 (0.83 - 0.90)
	>10 years	11	0.90 (0.84 - 0.96)	0.84 (0.81 - 0.87)	0.81 (0.77 - 0.84)

Table 6. Average reader performance when aided by BlineSlide across reader characteristics. Metrics are reported as [point estimate (95% confidence interval)]. Analyses are not powered to detect statistically significant differences and are not intended to support performance claims for any individual cohort (see accompanying text).

Conclusion

BlineSlide is substantially equivalent in intended use, design, principles of operation, technological characteristics, and safety features to the predicate device.

The special controls for 21 CFR 892.2060 are satisfied by demonstrating the effectiveness of the device in both standalone and clinical testing, showing the superiority of aided versus

unaided reader performance in the clinical testing, providing appropriate software and cybersecurity documentation, and communicating appropriate information in the labeling.

BlineSlide is as safe and as effective as the predicate device when used as intended.