



October 6, 2025

Deep Breathe Inc.  
Robert Arntfield  
CEO and Founder  
45 King St #300  
London, ON N6A 1B8  
Canada

Re: K252007

Trade/Device Name: BlineSlide  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: QIH  
Dated: September 5, 2025  
Received: September 5, 2025

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](#).

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 for

Jessica Lamb, Ph.D.  
Assistant Director  
Imaging Software Team  
DHT8B: Division of Radiological Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K252007

Device Name

BlineSlide

Indications for Use (Describe)

The device 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared: 2025-06-26

## Subject Device

Name of Device: BlineSlide  
Manufacturer: Deep Breathe Inc.  
Classification Name: Automated Radiological Image Processing Software  
Regulation Number: 21 CFR 892.2050  
Regulatory Class: II  
Product Code: QIH

## Predicate Device

Name of Device: AI Platform  
Premarket Notification: K232501  
Manufacturer: Exo Imaging  
Classification Name: Automated Radiological Image Processing Software  
Regulation Number: 21 CFR 892.2050  
Regulatory Class: II  
Product Code: QIH

## Reference Device

Name of Device: Lumify Diagnostic Ultrasound System  
Premarket Notification: K223771  
Manufacturer: Philips  
Classification Name: Ultrasonic Pulsed Doppler Imaging System

Regulation Number: 21 CFR 892.1550  
Regulatory Class: II  
Product Code: IYN, IYO, ITX, QIH

## Device Description

Blineslide is a cloud service application that helps qualified users with image-based assessment of lung ultrasound (LUS) cines acquired from the anterior or anterolateral chest regions during a physician-led LUS examination of patients aged 18 years or older. It does not directly interface with ultrasound systems.

Blineslide takes as input user-uploaded B-Mode LUS video clips (cines) in MP4 format and allows users to detect the relevant medical parameters of structures and function (LUS artifacts). Key features of the software are:

- **B Line Artifact Module:** an AI-assisted tool for detecting the presence or absence of B line artifacts in LUS cines

Blineslide is incompatible with:

- Cines that are acquired from *Linear* array ultrasound transducers;
- Cines acquired at less than 18 frames per second;
- Cines that require more than 2048 megabytes of memory;
- Cines that are less than 2600 milliseconds in duration; and
- Cines that are greater than 7800 milliseconds in duration

Each of these exclusion criteria are automatically assessed by the software. If detected, an output of *Cannot Evaluate* is returned to the user to minimize the risk of false LUS artifact detections.

Blineslide does not perform any function that could not be accomplished by a trained user manually. Patient management decisions **should not be made** solely on the results of Blineslide's analysis.

## Indication for Use

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.

## Contraindications

None.

## 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 intensivists, emergency physicians, pulmonologists, general practitioners, or other clinicians interpreting the source lung ultrasound cines. This includes physicians working in a variety of settings, including urban, rural, and austere environments.

## Environment of Use

The environment of use includes any setting 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, outpatient clinics, and remote or austere environments where access to advanced imaging modalities may be limited.

## Compatible Ultrasounds

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

## 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:

| <b>Feature</b>             | <b>Subject Device</b><br>Blineslide  | <b>Predicate Device</b><br>AI Platform<br>(K232501)  | <b>Reference Device</b><br>Lumify<br>Diagnostic<br>Ultrasound<br>System<br>(K223771)            | <b>Discussion of Differences</b>  |
|----------------------------|--|--|---|---|
| <b>Indications for Use</b> | The device is intended for noninvasive processing of ultrasound images to detect, measure, and calculate | The device is intended for noninvasive processing of ultrasound images to detect, measure, and calculate | The device is intended for diagnostic ultrasound imaging in B (2D), Pulsed Wave, Color Doppler, | Equivalent to predicate. The subject device is intended for use in patients aged 18 years and older. The predicate device |

|  |   |  |  |   |
|--|---|--|--|---|
|  | relevant medical parameters of structures and function of patients aged 18 years or older with suspected disease.   | relevant medical parameters of structures and function of adult patients with suspected disease. | Combined (B+Color), and M modes.   | is intended for adult patients aged 22 years and older. This difference in minimum patient age does not impact the intended use or raise new questions of safety and effectiveness. Comparisons with the reference device are focused on its merged B line artifact detection software feature. |
| <b>Principle of operation and technology</b> | Ultrasound image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical data intended for non-invasive analysis of ultrasound data |  |  | Identical.  |
| <b>Input</b>                                 | MP4   | DICOM  | Equivalent. The change in input format does not change the Intended Use. Both formats store the same ultrasound imaging data required for clinical interpretation. While DICOM includes additional metadata, this is not critical to the proposed device's |   |

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|   |  |  |  | functionality.   |
| <b>Scan type</b>                          | Multi-frame ultrasound images (cines)  | Single and multi-frame ultrasound images |  | Identical.   |
| <b>Image review</b>                       | Deep convolutional neural networks for segmentation or landmark detection                    |  |  | Identical.   |
| <b>Editing of outputs by user allowed</b> | Yes  |  |  | Identical.   |
| <b>Report creation</b>                    | Yes. A table summarizing the device outputs for each uploaded cine is displayed to the user. | Yes                                      |  | Identical.   |
| <b>Anatomical Sites</b>                   | Lungs  | Heart, Lungs                             | Lungs  | Equivalent to predicate. Restricting the anatomical site to the lungs does not change the Intended Use. Identical to reference device.   |
| <b>Lung artifacts detected</b>            | B line artifacts   | A line artifacts, B line artifacts       | B line artifacts   | Identical.   |
| <b>B line artifact detection</b>          | Detects the presence or absence of B lines   | Counts B lines                           | Counts B lines and detects the presence or absence of merged B lines | Equivalent. The updated task formulation does not change the Intended Use. The provided performance assessment for the B line artifact detection module demonstrates that this difference does not raise any |

|  |  |  |  |   |
|--|--|--|--|---|
|  |  |  |  | new questions of safety or effectiveness. |
|--|--|--|--|---|

In summary, the subject and predicate devices share the same Intended Use: noninvasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function in adult patients with suspected disease. The change in input type from DICOM to MP4 does not alter this, as both formats provide the necessary data for these assessments, nor does the shift from counting to detecting B-lines, as both methods assess the presence of a clinically relevant lung ultrasound artifact. These changes do not raise any new questions of safety or effectiveness, as evidenced by the performance testing results, which follow a protocol similar to that of the reference device.

Other features of the device, such as the scan type, ability to review images, edit/modify device outputs, and create reports, remain unchanged, further supporting the equivalence of the devices. The refinements in the subject device reflect an adaptation to support a broader range of clinical applications while maintaining its capability to process ultrasound images for relevant medical assessments. These modifications enhance usability without altering the device's Intended Use or safety profile. Hence, the subject device, BlineSlide, is determined to be substantially equivalent to the predicate device, AI Platform (K232501).

## 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 B Line Artifact Detection Module was successfully evaluated on a test dataset of 1005 cines encompassing diverse demographic and imaging variables. Cines were acquired from a variety of clinical sites in cities with diverse race and ethnicity populations.

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 B line 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, 25 clips met this criterion, representing only 2.4% of all cases considered. After exclusions, the final dataset comprised 326 positive class examples with B Line Artifacts Present and 679 negative class examples with B Line Artifacts Absent. 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.

|                    | <b>Reliability</b> |
|--------------------|--------------------|
| <b>Sensitivity</b> | 0.91 (0.88 – 0.94) |
| <b>Specificity</b> | 0.84 (0.81 – 0.86) |

**Table 2.** *Blineslide’s Reliability for Detecting the Presence of B Line Artifacts.*

Module performance was also assessed across a wide range of key cohorts, including: imaging characteristics (ultrasound vendor, transducer type, image quality), demographic variables (sex, age, body mass index), and artifact patterns (A lines, Z lines, B lines, No Pattern). The evaluation concluded that performance was consistent across clinically meaningful cohorts.

## Summary of Clinical Tests

The subject of this submission, Blineslide, did not require clinical testing due to the device type and classification.

# Conclusion

BlineSlide is substantially equivalent in intended use, design, principles of operation, technological characteristics, and safety features to the predicate device. The subject device is as safe and as effective as the predicate device, when used as intended.