



April 24, 2025

Exo Inc.  
Jacqueline Murray  
Senior Regulatory Affairs Specialist  
4201 Burton Drive  
Santa Clara, California 95054

Re: K243239  
Trade/Device Name: Lung AI (LAI001)  
Regulation Number: 21 CFR 892.2070  
Regulation Name: Medical image analyzer  
Regulatory Class: Class II  
Product Code: MYN  
Dated: October 10, 2024  
Received: March 21, 2025

Dear Jacqueline Murray:

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

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

510(k) Number (if known)

K243239

Device Name

Lung AI (LAI001)

Indications for Use (Describe)

Lung AI software device is a Computer-Aided Detection (CADE) tool designed to assist in the detection of consolidation/atelectasis and pleural effusion during the review of lung ultrasound scans.

The software is an adjunctive tool to alert users to the presence of regions of interest (ROI) with consolidation/atelectasis and pleural effusion within the analyzed lung ultrasound cine clip.

Lung AI is intended to be used on images collected from the PLAPS point, in accordance with the BLUE protocol.

The intended users are healthcare professionals who are trained and qualified in performing lung ultrasound and routinely perform lung ultrasounds as part of their current practice in a point-of-care environment—namely Emergency Departments (EDs). The device was not designed and tested with use environments representing EMTs and military medics.

Lung AI is not intended for clinical diagnosis and does not replace the healthcare provider's judgment or other diagnostic tests in the standard care for lung ultrasound findings. All cases where a Chest CT scan and/or Chest X-ray is part of the standard of care should undergo these imaging procedures, irrespective of the device output.

The software is indicated for adults only.

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.**

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**510(k) Summary****K243239**

## General Information

|                              |                                            |
|------------------------------|--------------------------------------------|
| <b>510(k) Sponsor</b>        | Exo Inc.                                   |
| <b>Address</b>               | 4201 Burton Drive<br>Santa Clara, CA 95054 |
| <b>Correspondence Person</b> | Jacqueline Murray                          |
| <b>Contact Information</b>   | jmurray@exo.inc<br>Cell: +1 236-838-5056   |
| <b>Date Prepared</b>         | April 24th 2025                            |

## Proposed Device

|                            |                        |
|----------------------------|------------------------|
| <b>Proprietary Name</b>    | Lung AI (LAI001)       |
| <b>Common Name</b>         | Lung AI                |
| <b>Classification Name</b> | Medical Image Analyzer |
| <b>Regulation Number</b>   | 21 CFR 892.2070        |
| <b>Product Code</b>        | MYN                    |
| <b>Regulatory Class</b>    | II                     |

## Predicate Device

|                               |                        |
|-------------------------------|------------------------|
| <b>Proprietary Name</b>       | Lung-CAD               |
| <b>Premarket Notification</b> | K230085                |
| <b>Classification Name</b>    | Medical Image Analyzer |
| <b>Regulation Number</b>      | 21 CFR 892.2070        |
| <b>Product Code</b>           | MYN                    |
| <b>Regulatory Class</b>       | II                     |

**Device description**

Lung AI is a Computer-Aided Detection (CADe) tool designed to assist in the analysis of lung ultrasound images by suggesting the presence of consolidation/atelectasis and pleural effusion in a scan. This adjunctive tool is intended to aid users to detect the presence of regions of interest (ROI) with consolidation/atelectasis and pleural effusion. However, the device does not provide a diagnosis for any disease nor replace any diagnostic testing in the standard of care.

The lung AI module processes Ultrasound cine clips and flags any evidence of pleural effusion and/or consolidation/atelectasis present without aggregating data across regions or making any patient-level decisions. For positive cases, a single ROI per clip from a frame with the largest pleural effusion (or consolidation/atelectasis) is generated as part of the device output. Moreover, the ROI output is for visualization only and should not be relied on for precise anatomical localization. The final decision regarding the overall assessment of the information from all regions/clips remains the responsibility of the user. Lung AI is intended to be used on clips collected only from the PLAPS point, in accordance with the BLUE protocol.

Lung AI is developed as a module to be integrated by another computer programmer into their legally marketed ultrasound imaging device. The software integrates with third-party ultrasound imaging devices and functions as a post-processing tool. The software does not include a built-in viewer; instead, it works within the existing third-party device interface.

Lung AI is validated to meet applicable safety and efficacy requirements and to be generalizable to image data sourced from ultrasound transducers of a specific frequency range.

The device is intended to be used on images of adult patients undergoing point-of-care (POC) lung ultrasound scans in the emergency departments due to suspicion of pleural effusion and/or consolidation/atelectasis. It is important to note that patient management decisions should not be made solely on the results of the Lung AI analysis.

The underlying deep learning models were trained on a diverse dataset of 3,453 ultrasound cine clips from 1,036 patients across Canada, the U.S., and South America. This dataset includes common pathologies encountered in point-of-care settings, such as emergency departments and ICUs. The clinical confounders in the development set include cases of Pneumonia, Pulmonary Embolism, Congestive Heart Failure (CHF), Tamponade, Covid19, ARDS, and COPD. The ultrasound manufacturers included SonoSite, Philips Lumify, GE, Mindray, Clarius, Exo and Butterfly.

### **Indications for Use**

Lung AI software device is a Computer-Aided Detection (CADe) tool designed to assist in the detection of consolidation/atelectasis and pleural effusion during the review of lung ultrasound scans.

The software is an adjunctive tool to alert users to the presence of regions of interest (ROI) with consolidation/atelectasis and pleural effusion within the analyzed lung ultrasound cine clip. Lung AI is intended to be used on images collected from the PLAPS point, in accordance with the BLUE protocol.

The intended users are healthcare professionals who are trained and qualified in performing lung ultrasound and routinely perform lung ultrasounds as part of their current practice in a point-of-care environment - namely Emergency Departments (EDs). The device was not designed and tested with use

environments representing EMTs and military medics.

Lung AI is not intended for clinical diagnosis and does not replace the healthcare provider's judgment or other diagnostic tests in the standard care for lung ultrasound findings. All cases where a Chest CT scan and/or Chest X-ray is part of the standard of care should undergo these imaging procedures, irrespective of the device output.

The software is indicated for adults only.

### Comparison of Technological Characteristics with the Predicate Device

| Feature/ Function                     | Subject Device:<br>Lung AI                                                                                                             | Predicate Device<br>Lung-CAD by Imagen Technologies<br>(K230085)                                                          |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Image Modality                        | Ultrasound                                                                                                                             | Digital X-ray                                                                                                             |
| Study Type                            | Chest                                                                                                                                  | Chest                                                                                                                     |
| Scan type                             | Multi-frame ultrasound images                                                                                                          | Digital X-ray images                                                                                                      |
| Clinical Output                       | Identify and mark regions of interest (ROIs) on lung Ultrasound                                                                        | Identify and mark regions of interest (ROIs) on chest radiographs and label the box around the ROI as lung hyperinflation |
| Intended User Workflow                | Device is intended for use as a concurrent reading aid for trained healthcare professionals qualified in interpreting lung ultrasounds | Device intended for use as a concurrent reading aid for physicians interpreting chest radiographs                         |
| Patient Population                    | Adults                                                                                                                                 | Adults                                                                                                                    |
| Principle of Operation and Technology | Artificial intelligence, including non-adaptive machine learning algorithms trained with clinical data                                 | Artificial intelligence                                                                                                   |

|                |                                                                                                                               |                          |
|----------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| AI Algorithm   | Supervised Deep Learning including Deep Convolutional Neural Networks for Segmentation, Landmark Detection and Classification | Supervised Deep Learning |
| Intended Users | Trained healthcare professionals                                                                                              | Physicians               |

### Performance Data

The safety and performance of the Lung AI device has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304:2006/AC:2015 - *Medical device software – Software life cycle processes*, and the following FDA guidances:

- Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff
- *Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data Premarket Notification [510(k)] Submissions*
- *Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions.*
- *Cybersecurity testing was performed in accordance with Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.*

### Bench Testing

The standalone performance of the Lung AI device was successfully evaluated on test data encompassing diverse demographic variables, including gender, age (ranging from 21 to 96), and ethnicity from multiple clinical sites in metropolitan cities with diverse racial patient populations. To ensure unbiased data, cases were selected consecutively in the order they were received. The dataset was then enriched with abnormal cases (to have at least 30% abnormal cases per center) to ensure sufficient representation of clinically relevant conditions in line with FDA guidelines.

465 lung scans from 359 unique patients were retrospectively collected from 6 imaging centers in the U.S. and Canada, with more than 50% of the data coming from U.S. centers. There were 239 positive and 226 negative cases for pleural effusion. There were 247 positive and 218 negative cases for consolidation/atelectasis. Adjustments were made to account for intra-subject correlation in calculating confidence intervals.



The presence of consolidation, atelectasis, and pleural effusion was evaluated in subjects with images acquired during routine clinical practice using cart-based and portable ultrasound devices (with frequencies ranging from 1.5 to 7 MHz).

The reference standard was established by two US board-certified experts, experienced in point-of-care ultrasound, reading lung ultrasound scans and diagnostic radiology. The experts indicated their independent assessment of the presence/absence of each indication per cine clip. Adjudication, in case of disagreement, was provided by a third expert.

The experts also provided annotations for the bounding boxes to evaluate localization accuracy.

The test data was entirely separated from the training/validation datasets and was not used for any part of the training.

The performance of Lung AI for consolidation/atelectasis and pleural effusion suggestions when compared to reference data is summarized in Table 1 below:

**Table 1.** Summary of Lung AI performance

| Lung Finding                | Detection Performance Metric   |
|-----------------------------|--------------------------------|
| Pleural Effusion            | Se = 0.97 (95% CI 0.94 – 0.99) |
|                             | Sp = 0.91 (95% CI 0.87 – 0.96) |
| Consolidation / Atelectasis | Se = 0.97 (95% CI 0.94 – 0.99) |
|                             | Sp = 0.94 (95% CI 0.90 – 0.98) |

The localization performance of the Lung AI is assessed using sensitivity and specificity, along with their corresponding confidence intervals, based on the IoU overlap between the device (AI-ROI) and the ground truth (GT-ROI). True positive is when a predicted bounding box (AI-ROI) has an IoU  $\geq 0.5$  with the GT-ROI. The localization performance of Lung AI is summarized in Table 2 below:

**Table 2.** Summary of Lung AI localization performance

| Lung Finding                | Localization Performance Metric |
|-----------------------------|---------------------------------|
| Pleural Effusion            | Se = 0.85 (95% CI 0.80 – 0.89)  |
|                             | Sp = 0.91 (95% CI 0.87 – 0.96)  |
| Consolidation / Atelectasis | Se = 0.86 (95% CI 0.81 – 0.90)  |
|                             | Sp = 0.94 (95% CI 0.90 – 0.98)  |

The device performance was also assessed across a wide range of ultrasound device manufacturers (including Sonosite, Exo and Philips) and demographic subgroups (gender, age, sites, confounders). The confounders included pneumonia, CHF, Covid 19, ARDS, pulmonary edema, pulmonary embolism, tachypnea, COPD). Additional subgroup analysis included scan laterality (right vs left PLAPs view) and different depths of lung scans. The evaluation concluded that the device's performance was consistent among clinically meaningful subgroups. A detailed subgroup analysis is reported in the labelling.

### **MULTI-READER, MULTI-CASE (MRMC) STUDY**

Lung AI has been validated by a multi-reader, multi-case (MRMC) study. The study consisted of 6 readers with varying levels of training and experience as emergency physicians, who provided analysis on a randomized set of 322 unique patients, presented in two reading periods ("unaided" and "aided") and separated by a minimum 4-week washout period. In total, 748 cases were analyzed per reader for a total of 4488 cases overall.

The primary endpoint was an improvement of at least 2% in overall reader performance, as measured by AUC-ROC, when aided by the device. This study successfully met the acceptance criteria for the detection of consolidation/atelectasis and pleural effusion and fulfilled the design requirements for Lung AI. A summary of the MRMC results is presented below:

#### **Pleural Effusion MRMC results**

AUC-ROC: The MRMC analysis for detection of pleural effusion shows  $AUC_{unaided} = 0.93$  (95% CI .92 - .94) is improved to  $AUC_{aided} = 0.96$  (95% CI .95 - .98) with a AUC improvement of  $\Delta_{AUC-PEFF} = AUC_{aided} - AUC_{unaided} = 0.035$  (95% CI .025 - .047), which passes the acceptance criteria.

Sensitivity (Se): The MRMC analysis for detection of pleural effusion shows  $Se_{unaided} = 0.71$  (95% CI .68 - .75) is significantly improved to  $Se_{aided} = 0.88$  (95% CI .86 - .92) with a Se improvement of  $\Delta_{Se-PEFF} = Se_{aided} - Se_{unaided} = 0.18$  (95% CI .14 - .20)

Specificity (Sp): The MRMC analysis for detection of pleural effusion shows  $Sp_{unaided} = 0.96$  (95% CI .95 - .97) is slightly decreased to  $Sp_{aided} = 0.93$  (95% CI .88 - .95) with  $\Delta_{Sp-CONS} = Sp_{aided} - Sp_{unaided} = -0.03$  (95% CI -.08 to -.02)

#### **Consolidation/atelectasis MRMC results:**

AUC-ROC: The MRMC analysis for detection of consolidation shows  $AUC_{unaided} = 0.92$  (95% CI .91 - .96) is improved to  $AUC_{aided} = 0.95$  (95% CI .94 - .98) with a AUC improvement of  $\Delta_{AUC-CONS} = AUC_{aided} - AUC_{unaided} = 0.028$  (95% CI .0201 - .0403), which passes the acceptance criteria.

Sensitivity (Se): The MRMC analysis for detection of consolidation shows  $Se_{unaided} = 0.73$  (95% CI .72 - .80) is improved to  $Se_{aided} = 0.89$  (95% CI .88 - .93) with a significant Se improvement of  $\Delta_{Sp-CONS} = Se_{aided} - Se_{unaided} = 0.16$  (95% CI .13 - .19)

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Specificity (Sp): The MRMC analysis for detection of consolidation shows  $Sp_{\text{unaided}} = 0.92$  (95% CI .88 – .93) is slightly decreased to  $Sp_{\text{aided}} = 0.91$  (95% CI .87 – .93) with  $\Delta_{\text{Sp-CONS}} = Sp_{\text{aided}} - Sp_{\text{unaided}} = -0.008$  (95% CI -.01 to -.005)

### Conclusions

Exo's Lung AI is substantially equivalent in intended use and technological characteristics to the predicate device as demonstrated by the conclusions drawn from the standalone and clinical studies. There are no different questions of safety and/or effectiveness introduced by Lung AI when used as intended.