July 8, 2026

Neurocareai, Inc. (Dba Savelife.Ai)
Junaid Kalia
Chief Executive Officer
1740 Lonesome Dove Dr.
Prosper, Texas 75078

Re: K253751
Trade/Device Name: CXRDetectAI
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: June 8, 2026
Received: June 8, 2026

Dear Junaid Kalia:

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 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
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253751

Please provide the device trade name(s).

CXRDetectAI

Please provide your Indications for Use below.

CXRDetectAI is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected abnormalities i.e., pleural effusion, and/or pneumothorax. The device uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides study-level output available in the hospital PACS/workstation for worklist prioritization or triage.

As a passive notification for prioritization-only software tool within standard of care workflow, CXRDetectAI does not send a proactive alert directly to the appropriately trained specialists. CXRDetectAI is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

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)

K253751

510(k) Summary of CXRDetectAI
by
NEUROCAREAI INC

Applicant Name: NEUROCAREAI INC (DBA SaveLife.AI)
1740 Lonesome Dove Dr
Prosper, TX 75078 USA
Phone Number: +1 (214) 346-6083
Whatsapp: +1 (469) 954-0346

Contact Person: Junaid Kalia
Chief Executive Officer
Email: junaidkalia@neurocare.ai

Date Prepared: June 8, 2026

Device Name and Classification

Name of Device: CXRDetectAI

Classification Name: Radiological Computer Aided Triage and Notification Software

Common or Usual Name: Radiological Computer Assisted Prioritization Software for Lesions

Classification Panel: Radiology

Regulation Number: 21 CFR 892.2080

Regulatory Class: Class II

Product Code: QFM

Predicate Device:

Manufacturer	Device Name	Product Code	Application Number
Lunit Inc.	Lunit INSIGHT CXR Triage	QFM	K211733

Device Description:
CXRDetectAI is a radiological computer-assisted prioritization software that utilizes AI-based image analysis algorithm to identify pre-specified critical findings (pleural effusion, and/or pneumothorax) on frontal (AP and PA views) chest X-ray images and flag the images in the hospital PACS/workstation to enable worklist prioritization by the appropriately trained specialists who are qualified to interpret chest radiographs. The software does not alter the order or remove cases from the reading queue.

Chest radiographs are automatically received from the hospital PACS (Picture Archiving and Communication System) and processed by the device for analysis. Following receipt of chest radiographs, the software device automatically analyses each image to detect features suggestive of pleural effusion, and/or pneumothorax. Based on the analysis result, the software notifies hospital PACS/workstation for the presence of the critical findings as indicating either “critical” or “routine”. This would allow the appropriately trained specialists to group suspicious exams together that may potentially benefit for their prioritization.

Chest radiographs without an identified anomaly are placed in the worklist for routine review, which is the current standard of care. CXRDetectAI can detect more than one critical finding per radiograph. The device does not provide any proactive alerts and is not intended to direct attention to specific portions of the image. The results are not intended to be used on a standalone basis for clinical decision-making nor is it intended to rule out the target conditions or otherwise preclude clinical assessment of x-ray cases.

Intended Use:
The CXRDetectAI software is designed to detect and classify the presence of pleural effusion, and/or pneumothorax in frontal chest X-ray images. The results are presented in the hospital PACS or workstation for prioritized review by trained specialists. Patients are flagged with a “critical” tag if any of the pre-specified critical findings are identified. Utilizing an artificial intelligence algorithm, the device analyzes images in parallel with the standard of care interpretation workflow, enabling worklist prioritization to facilitate the earlier review and diagnosis of critical patients compared to routine practices.

Indications for Use:
CXRDetectAI is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected abnormalities i.e., pleural effusion, and/or pneumothorax. The device uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides study-level output available in the hospital PACS/workstation for worklist prioritization or triage.

As a passive notification for prioritization-only software tool within standard of care workflow, CXRDetectAI does not send a proactive alert directly to the appropriately trained specialists. CXRDetectAI is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

There is a minor difference between the subject and predicate device Lunit INSIGHT CXR Triage (K211733) in their indications for use. The predicate device is indicated for use to analyze chest X-rays for features suggestive of pre-specified critical findings and provide case-level output available in the PACS/Workstation, whereas CXRDetectAI provides study-level output in the PACS/Workstation after analyzing for features suggestive of same

pre-specified critical findings. While the level of output provided by both devices slightly differ, the intended use of the device which is to provide passive notification for triage and prioritization for time sensitive radiologic findings in the analyzed chest X-ray is the same. Additionally, the type of output i.e., prioritization flag for critical studies and secondary capture of the finding is also same in both devices.

Comparison of Technological Characteristics:
Both the CXRDetectAI and the predicate device; Lunit INSIGHT CXR Triage are software only devices that use Artificial intelligence (AI) algorithms and are intended to aid in triage and prioritization of radiological images.

At a high level, the subject and the predicate devices have the same principle of operation and underlying technological characteristics:

1. Artificial Intelligence Algorithm
2. Triage and Prioritization Software

There are no notable technological differences between the subject and the predicate device. Both devices are designed to identify pre-specified abnormalities, in chest X-rays to prioritize the review of critical cases. They both operate on frontal chest radiographs (PA and/or AP views) and present results within the hospital PACS to enable worklist prioritization.

Both devices target the same intended user and patient populations, utilizing the same imaging modality—chest X-rays. As passive notification tools focused on prioritization, neither device sends proactive alerts directly to the intended user. Additionally, neither device alters the standard of care image workflow after integration with hospital systems, removes cases from the worklist queue, or marks, highlights, or draws attention to specific regions of the analyzed chest X-ray.

Neither device is intended to serve as a standalone diagnostic tool. Instead, their outputs are solely for prioritization purposes, with the actual diagnosis relying on specialists performing standard-of-care image interpretation. As both devices use proprietary AI algorithms, there are assumed differences in the algorithmic components, as well as minor differences in the specific formats of the outputs provided to users. However these minor differences do not raise any new questions of safety and effectiveness and therefore do not affect the substantial equivalence claim of the subject device with the predicate device.

A table comparing the key features of the subject and predicate device is provided below:

Parameters	Subject Device CXRDetectAI	Predicate Device Lunit INSIGHT CXR Triage
Device classification	Radiological Computer Assisted Prioritization Software, Class II, QFM	Radiological Computer Assisted Prioritization Software, Class II, QFM
Indications for use/Intended Use	CXRDetectAI is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the	Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes

	presence of pre-specified suspected abnormalities i.e., pleural effusion, and/or pneumothorax. The device uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides study-level output available in the hospital PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, CXRDetectAI does not send a proactive alert directly to the appropriately trained specialists. CXRDetectAI is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.	adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.
Notification only, parallel workflow tool	Yes	Yes
Targeted clinical condition, anatomy, and modality	Pleural effusion, pneumothorax Chest/Lung Frontal Chest X-ray	Pleural effusion, pneumothorax Chest/Lung Frontal Chest X-ray
Targeted user population	Appropriately trained radiologists, medical specialists or pulmonologists who are qualified to interpret chest radiographs.	Appropriately trained medical specialists who are qualified to interpret chest radiographs.
Algorithm for pre-specified critical findings detection	AI algorithm designed to detect pleural effusion, and pneumothorax in chest X-ray images. CXRDetectAI uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.	AI algorithm designed to detect pleural effusion and pneumothorax in chest X-ray images. Lunit INSIGHT CXR Triage uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.
Radiological images format	DICOM	DICOM

Computational Platform	CXRDetectAI is designed as a software module that can be deployed with PACS for both On Premise or On Cloud integration options.	Lunit INSIGHT CXR Triage is designed as a software module that can be deployed on several computing and X-ray imaging platforms such as radiological imaging equipment, PACS, On Premise or On Cloud.
Device output in case of positive detection	When deployed with PACS, CXRDetectAI automatically runs after image acquisition and prioritizes and displays the analysis result through the worklist interface of PACS/Workstation. No markup on original image. Secondary capture (OT file) of the finding along with SR report.	When deployed on other radiological imaging equipment, Lunit INSIGHT CXR Triage automatically runs after image acquisition and prioritizes and displays the analysis result through the worklist interface of PACS/Workstation. No markup on original image. Secondary capture of the finding. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems), an on-device, technologist notification indicating which cases were flagged by Lunit INSIGHT CXR Triage in PACS, is generated 15 minutes after interpretation by the user. The ondevice notification is contextual and does not provide any diagnostic information. It is not intended to inform any clinical decision, prioritization, or action to the technologist.
Notification (i.e., recipient, timing and means of notification)	Passive notification. Images with suspicion of pleural effusion, and/or pneumothorax are flagged in PACS/workstation.	Passive notification. Images with suspicion of pleural effusion and/or pneumothorax are flagged in PACS/workstation.
Where generated results (i.e., DICOM files) are stored	PACS/Workstation	PACS/Workstation
Performance level – Performance Time	The performance time of the CXRDetectAI **For Cloud Deployment** 9.32 seconds (95% CI: 9.20, 9.44) for pleural effusion and 9.19 seconds (95% CI: 9.07, 9.32) for pneumothorax	The performance time of the Lunit INSIGHT CXR Triage was 20.76 seconds (95% CI: 20.23 - 21.28) for pleural effusion and 20.45 seconds (95% CI: 19.99 - 20.92) for pneumothorax

	For Edge Device 4.86 seconds (95% CI: 4.80, 4.92) for pleural effusion and 4.78 seconds (95% CI: 4.71, 4.85) for pneumothorax **For ConnectAI App** 21.65 seconds (95% CI: 21.42, 21.88) for pleural effusion and 21.45 seconds (95% CI: 21.22, 21.69) for pneumothorax	
Performance level – accuracy of classification	**Pleural Effusion** ROC AUC > 0.95 AUC: 0.982 (95% CI: [0.975, 0.988]) Sensitivity: 96.4% (95% CI: [93.2%, 98.3%]) Specificity: 93.8% (95% CI: [91.5%, 95.6%]) **Pneumothorax** ROC AUC > 0.95 AUC: 0.979 (95% CI: [0.968, 0.989]) Sensitivity: 97.4% (95% CI: [94.0%, 99.1%]) Specificity: 96.8% (95% CI: [95.1%, 98.0%])	**Pleural Effusion** ROC AUC > 0.95 AUC: 0.9686 (95% CI: [0.9547, 0.9824]) Sensitivity 89.86% (95% CI: [86.72, 93.00]) Specificity 93.48% (95% CI: [91.06, 95.91]) **Pneumothorax** ROC AUC > 0.95 AUC: 0.9630 (95% CI: [0.9521, 0.9739]) Sensitivity 88.92% (95% CI: [85.60, 92.24]) Specificity 90.51% (95% CI: [88.18, 92.83])

Performance Data:

Software Testing- Non Clinical

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation level for this device is Basic Documentation.

Performance Testing - Clinical

Clinical studies were conducted on retrospectively collected Chest X-rays to evaluate the performance of CXRDetectAI for triaging of pneumothorax, and pleural effusion. The studies were conducted with the chest X-ray dataset that was totally independent from the training dataset and represents the vast US population. A total of 839 anonymized chest radiographs collected from Segmed with recognizable distribution of both pre-specified abnormalities (247 cases for pleural effusion, and 190 cases for pneumothorax) and other confounders were used in the standalone performance testing and device performance time estimation. The dataset consisted of 50.7% males and 49.3% females. The cases were aged from 22 years to above 85 years with a fair distribution of 25.6% studies in age group 22 to 44 years, 39.6% studies in age group 45 to 64 years, 28.4% studies in age group 65 to 84 years, and 6.4% studies in patients over 85 years. The test dataset contains 162 chest x-ray studies with small pleural effusion (<

500ml), 61 studies with moderate pleural effusion (~ 500ml to 1500ml), and 24 studies with large pleural effusion (> 1500ml). Similarly the test dataset contains 23 chest x-ray studies with small pneumothorax (< 3cm), and 167 studies with large pneumothorax (≥ 3cm). Moreover, the dataset contains 146 unilateral pleural effusion studies, and 101 bilateral pleural effusion studies. Similarly, the dataset contains 179 unilateral pneumothorax studies and 11 bilateral pneumothorax studies. The dataset consisted of common clinical confounders such as presence of hardware/artifacts (233 studies for artifacts cohort and 221 studies for devices cohort), atelectasis (215 studies), consolidation (148 studies), edema (18 studies), emphysema (28 studies), fibrosis (96 studies), infiltration (78 studies), lung lesion (8 studies), lung opacity (39 studies), nodule (263 studies), mass (37 studies), and pleural thickening (21 studies). The dataset was also obtained from various X-ray device manufacturers like Samsung Electronics (44.0%), FUJIFILM Corporation (14.2%), Canon Inc. (8.2%), GE Healthcare (6.9%), Konica Minolta (6.8%), KODAK (4.6%), SIEMENS (4.3%), Carestream Health, Inc. (4.2%), Rayence (2.1%), Philips Medical Systems (2.0%), and had minor contributions (less than 1%) from IRAY, Agfa-Gevaert AG, Varian, Swissray, Agfa, Agfa-Gevaert and Oehm und Rehbein GmbH to ensure consistent performance and generalizability.

Sensitivity, specificity, ROC AUC and accuracy were calculated as primary endpoints with 95% clopper-pearson confidence interval, comparing the CXRDetectAI's output to the ground truth as established by three US board certified Radiologists.

Pleural Effusion:
The study dataset included a total of 839 studies (247 studies with pleural effusion and 592 studies without pleural effusion) from various parts of the US. CXRDetectAI in triaging scans with findings suspicious of pleural effusion met the pre-specified acceptance criteria in the overall study population: both the point estimate and the lower bound of the 95% confidence interval for sensitivity and specificity exceeded 80%, prediction accuracy exceeded 80%, and the AUC exceeded 0.95 with AUC: 0.982 (95% CI: [0.975, 0.988]), Sensitivity 96.4% (95% CI: [93.2%, 98.3%]) and Specificity 93.8% (95% CI: [91.5%, 95.6%]). Whereas the predicate device; Lunit INSIGHT CXR Triage's performance for pleural effusion was ROC AUC 0.9686 (95% CI: 0.9547 - 0.9824), Sensitivity 89.86% (95% CI: 86.72 - 93.00) and Specificity 93.48% (95% CI: 91.06 - 95.91).

The device's generalizability was ensured by performing subgroup analyses. The results for pleural effusion were consistent in both genders, across various manufacturers, confounder cohorts, intended population, races, various pleural effusion sizes, literality and US regions as shown in tables below:

Device Performance by Age			
Age Range (Years)	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
22 to 44	95.7% [78.1%, 99.9%]	95.8% [92.0%, 98.2%]	0.983 [0.964, 0.995]
45 to 64	93.8% [86.2%, 98.0%]	92.8% [88.9%, 95.7%]	0.979 [0.967, 0.99]
65 to 84	98.1% [93.2%, 99.8%]	93.3% [87.6%, 96.9%]	0.983 [0.968, 0.995]
85 and above	97.4% [86.5%, 99.9%]	86.7% [59.5%, 98.3%]	0.968 [0.906, 1.00]

Device Performance by Gender			
Gender	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Male	96.6% [92.1%, 98.9%]	90.4% [86.3%, 93.5%]	0.972 [0.958, 0.984]
Female	96.1% [90.3%, 98.9%]	96.8% [94.2%, 98.5%]	0.991 [0.983, 0.996]

Device Performance by Manufacturer			
Manufacturer	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Samsung Electronics	97.7% [92.0%, 99.7%]	97.9% [95.4%, 99.2%]	0.995 [0.991, 0.999]
FUJIFILM Corporation	92.9% [82.7%, 98.0%]	81.0% [69.1%, 89.8%]	0.935 [0.887, 0.973]
Canon Inc	100% [84.6%, 100%]	97.9% [88.7%, 99.9%]	0.988 [0.96,1.00]
GE Healthcare	100% [81.5%, 100%]	90.0% [76.3%, 97.2%]	0.965 [0.915,1.00]
Konica Minolta	94.1% [71.3%, 99.9%]	85.0% [70.2%, 94.3%]	0.951 [0.89, 0.99]
KODAK	100% [66.4%, 100%]	96.7% [82.8%, 99.9%]	0.996 [0.98, 1.00]
SIEMENS	100% [54.1%, 100%]	90.0% [73.5%, 97.9%]	0.961 [0.879,1.00]
Carestream Health, Inc	87.5% [47.3%, 99.7%]	92.6% [75.7%, 99.1%]	0.986 [0.944, 1.00]

Device Performance by Race			
Race	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
White	94.2% [87.8%, 97.8%]	90.2% [84.5%, 94.3%]	0.975 [0.959, 0.987]
Black	100.0% [47.8%, 100.0%]	91.7% [61.5%, 99.8%]	0.967 [0.850, 1.000]
Unknown	97.8% [93.8%, 99.5%]	95.6% [93.2%, 97.4%]	0.986 [0.977, 0.993]

Device Performance by Source Location

Location	Sensitivity [95% CI]	Specificity [95% CI]	AUC [95% CI]
us_east	98.0% [92.8%, 99.8%]	98.0% [95.8%, 99.3%]	0.995 [0.990, 0.999]
us_midwest	94.7% [86.9%, 98.5%]	81.5% [72.9%, 88.3%]	0.941 [0.909, 0.968]
us_northwest	88.2% [63.6%, 98.5%]	93.4% [84.1%, 98.2%]	0.969 [0.929, 0.995]
us_southwest	100.0% [82.4%, 100.0%]	98.3% [90.9%, 100.0%]	0.990 [0.963, 1.000]
us_telerad	95.0% [75.1%, 99.9%]	83.3% [67.2%, 93.6%]	0.939 [0.871, 0.987]
us_southeast	100.0% [81.5%, 100.0%]	100.0% [84.6%, 100.0%]	1.000 [1.000, 1.000]

Device Performance by Pleural Effusion Size and Laterality				
Subgroup	**Category**	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Size	Large (>1500ml)	100.0% [85.8%, 100.0%]	93.8% [91.5%, 95.6%]	0.989 [0.979, 0.996]
	Moderate (~500–1500 ml)	95.1% [86.3%, 99.0%]	93.8% [91.5%, 95.6%]	0.983 [0.974, 0.990]
	Small (<500ml)	96.3% [92.1%, 98.6%]	93.8% [91.5%, 95.6%]	0.981 [0.973, 0.988]
Laterality	Bilateral	98.0% [93.0%, 99.8%]	93.8% [91.5%, 95.6%]	0.981 [0.973, 0.988]
	Unilateral	95.2% [90.4%, 98.1%]	93.8% [91.5%, 95.6%]	0.983 [0.975, 0.989]

Device Performance by Imaging Artifacts and Medical Devices			
Subgroup	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Artifacts	93.8% [87.7%, 97.5%]	75.8% [67.2%, 83.2%]	0.913 [0.874, 0.946]

Medical Devices	94.3% [88.1%, 97.9%]	74.8% [65.8%, 82.4%]	0.909 [0.868, 0.940]

Device Performance by Confounder Cohort			
Confounder	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Mass	100.0% [66.4%, 100.0%]	92.9% [76.5%, 99.1%]	0.972 [0.910, 1.000]
Nodule	97.7% [91.9%, 99.7%]	97.2% [93.5%, 99.1%]	0.992 [0.983, 0.999]
Atelectasis	95.1% [88.9%, 98.4%]	81.4% [73.0%, 88.1%]	0.941 [0.909, 0.966]
Consolidation	94.9% [88.5%, 98.3%]	84.0% [70.9%, 92.8%]	0.957 [0.923, 0.986]
Edema	100.0% [75.3%, 100.0%]	100.0% [47.8%, 100.0%]	1.000 [1.000, 1.000]
Emphysema	100.0% [63.1%, 100.0%]	90.0% [68.3%, 98.8%]	0.975 [0.917, 1.000]
Fibrosis	94.6% [81.8%, 99.3%]	89.8% [79.2%, 96.2%]	0.968 [0.933, 0.991]
Infiltration	100.0% [89.1%, 100.0%]	93.5% [82.1%, 98.6%]	0.979 [0.945, 1.000]
Lung Lesion	100.0% [29.2%, 100.0%]	100.0% [47.8%, 100.0%]	1.000 [1.000, 1.000]
Lung Opacity	90.9% [58.7%, 99.8%]	100.0% [87.7%, 100.0%]	1.000 [1.000, 1.000]
Pleural Thickening	100.0% [79.4%, 100.0%]	100.0% [47.8%, 100.0%]	1.000 [1.000, 1.000]

In the 73 studies that had pleural effusion with combination of pneumothorax co-existing, performance accuracy of detecting pleural effusion was maintained at: AUC of 0.999 (95% CI: [0.997, 1.000]).

Justification of Sub-Group Performance (Pleural Effusion):
In the overall study population the device met all acceptance criteria across the full 95% confidence interval. In the majority of subgroups the point estimates meet the criteria and the wide confidence intervals are a direct consequence of the small number of positive or normal studies in the limiting subgroup for example the 22 to 44 years and 85+ years age groups; the KODAK, SIEMENS, Carestream Health, Inc., GE Healthcare and Konica Minolta manufacturers; the Black race subgroup (n=17); and the us_northwest region; where a single classification shifts the estimate by several percentage points and widens the interval. These reflect statistical uncertainty from limited sample size rather than reduced performance, and the point estimates remain concordant with the better-populated subgroups.

A small number of adequately powered subgroups show a genuine, mechanistically explained effect confined to specificity and the specificity-dependent AUC (i.e., an elevated false-positive rate rather than missed disease). Pleural effusion detection on FUJIFILM Corporation studies (specificity 81.0%, AUC 0.935; n=119) is attributable to vendor-specific low-frequency image rendering and is supported by an internal control - preserved high performance for high-frequency pneumothorax features on the same manufacturer's studies. The us_midwest and us_telerad regions reflect documented case-mix and acquisition-context effects (a higher proportion of basal confounders such as atelectasis and consolidation, and portable/supine ICU and emergency examinations) that act predominantly on the non-diseased population. The Atelectasis and Consolidation confounder cohorts show the same overlap, where basilar opacification and costophrenic-recess blunting radiographically mimic effusion. The imaging-artifact and implanted-device cohorts (specificity 75.8% and 74.8%; AUC 0.913 and 0.909) reflect overlying hardware that produces disease-like features on non-diseased studies. In all of these subgroups sensitivity is preserved (disease is reliably detected), and the modest specificity reduction is mitigated by the device's intended use as an adjunct to clinician interpretation rather than a standalone diagnostic.

Pneumothorax:

The study dataset included a total of 839 studies (190 studies with pneumothorax and 649 studies without pneumothorax) from various parts of the US. CXRDetectAI in triaging scans with findings suspicious of pneumothorax met the pre-specified acceptance criteria in the overall study population: both the point estimate and the lower bound of the 95% confidence interval for sensitivity and specificity exceeded 80%, prediction accuracy exceeded 80%, and the AUC exceeded 0.95 with AUC: 0.979 (95% CI: [0.968, 0.989]), Sensitivity 97.4% (95% CI: [94.0%, 99.1%]) and Specificity 96.8% (95% CI: [95.1%, 98.0%]). Whereas the predicate device; Lunit INSIGHT CXR Triage's performance for pneumothorax was ROC AUC 0.9630 (95% CI: 0.9521 - 0.9739), Sensitivity 88.92% (95% CI: 85.60 - 92.24) and Specificity 90.51% (95% CI: 88.18 - 92.83).

The device's generalizability was ensured by performing subgroup analyses. The results for pneumothorax were consistent in both genders, across various manufacturers, confounder cohorts, intended population, races, various pneumothorax sizes, literality and US regions as shown in tables below:

Device Performance by Age			
Age Range (Years)	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
22 to 44	94.4% [81.3%, 99.3%]	99.4% [96.9%, 100.0%]	0.986 [0.964, 1.00]
45 to 64	98.8% [93.3%, 100%]	96.4% [93.3%, 98.3%]	0.984 [0.97, 0.996]
65 to 84	98.3% [90.9%, 100%]	95.0% [90.7%, 97.7%]	0.965 [0.935, 0.99]
85 and above	92.9% [66.1%, 99.8%]	95.0% [83.1%, 99.4%]	0.964 [0.903, 1.00]

Device Performance by Gender			
Gender	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Male	99.2% [95.4%, 100%]	96.4% [93.7%, 98.2%]	0.982 [0.969, 0.992]
Female	94.4% [86.2%, 98.4%]	97.1% [94.7%, 98.6%]	0.974 [0.950, 0.991]

Device Performance by Manufacturer			
Manufacturer	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Samsung Electronics	95.0% [75.1%, 99.9%]	99.4% [97.9%, 99.9%]	0.993 [0.978, 1.00]
FUJIFILM Corporation	95.9% [88.5%, 99.1%]	100% [92.3%, 100%]	0.981 [0.955, 1.00]
Canon Inc	100% [59.0%, 100%]	91.9% [82.2%, 97.3%]	0.977 [0.931, 1.00]
GE Healthcare	100% [76.8%, 100%]	97.7% [88.0%, 99.9%]	0.989 [0.956, 1.00]
Konica Minolta	100% [90.5%, 100%]	95.0% [75.1%, 99.9%]	0.989 [0.960, 1.00]
KODAK	100% [15.8%, 100%]	89.2% [74.6%, 97.0%]	1.000 [1.000, 1.000]
SIEMENS	92.3% [64.0%, 99.8%]	87.0% [66.4%, 97.2%]	0.963 [0.869, 1.00]

Carestream Health, Inc	100% [75.3%, 100%]	90.9% [70.8%, 98.9%]	0.972 [0.911, 1.00]

Device Performance by Race			
Race	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
White	99.1% [95.3%, 100.0%]	95.4% [90.7%, 98.1%]	0.982 [0.963, 0.996]
Black	85.7% [42.1%, 99.6%]	90.0% [55.5%, 99.7%]	0.850 [0.591, 1.000]
Unknown	95.5% [87.3%, 99.1%]	97.3% [95.4%, 98.6%]	0.981 [0.967, 0.992]

Device Performance by Source Location			
Location	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
us_east	90.0% [68.3%, 98.8%]	98.7% [97.0%, 99.6%]	0.985 [0.962, 0.999]
us_midwest	99.2% [95.5%, 100.0%]	93.4% [84.1%, 98.2%]	0.959 [0.917, 0.991]
us_northwest	100.0% [75.3%, 100.0%]	96.9% [89.3%, 99.6%]	0.992 [0.974, 1.000]
us_southwest	90.0% [55.5%, 99.7%]	94.1% [85.6%, 98.4%]	0.937 [0.824, 0.998]
us_telerad	95.7% [78.1%, 99.9%]	87.9% [71.8%, 96.6%]	0.945 [0.881, 0.995]
us_southeast	100.0% [2.5%, 100.0%]	94.9% [82.7%, 99.4%]	0.949 [0.868, 1.000]

Device Performance by Pneumothorax Size and Laterality				
Subgroup	**Category**	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Size	Large (≥3cm)	98.2% [94.8%, 99.6%]	96.8% [95.1%, 98.0%]	0.981 [0.970, 0.990]

	Small (<3cm)	91.3% [72.0%, 98.9%]	96.8% [95.1%, 98.0%]	0.966 [0.938, 0.987]
Laterality	Bilateral	100.0% [71.5%, 100.0%]	96.8% [95.1%, 98.0%]	0.993 [0.986, 0.998]
	Unilateral	97.2% [93.6%, 99.1%]	96.8% [95.1%, 98.0%]	0.979 [0.968, 0.988]

Device Performance by Imaging Artifacts and Medical Devices			
Subgroup	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Artifacts	97.8% [93.8%, 99.6%]	90.4% [82.6%, 95.5%]	0.946 [0.909, 0.977]
Medical Devices	98.5% [94.7%, 99.8%]	89.7% [81.3%, 95.2%]	0.945 [0.906, 0.979]

Device Performance by Confounder Cohort			
Confounder	**Sensitivity [95% CI]**	**Specificity [95% CI]**	**AUC [95% CI]**
Mass	100.0% [29.2%, 100.0%]	97.1% [84.7%, 99.9%]	1.000 [1.000, 1.000]
Nodule	98.0% [89.4%, 99.9%]	95.8% [92.1%, 98.0%]	0.968 [0.945, 0.988]
Atelectasis	96.9% [91.3%, 99.4%]	91.5% [84.8%, 95.8%]	0.962 [0.936, 0.984]
Consolidation	98.0% [89.1%, 99.9%]	87.9% [79.8%, 93.6%]	0.948 [0.908, 0.979]
Edema	100.0% [15.8%, 100.0%]	100.0% [79.4%, 100.0%]	1.000 [1.000, 1.000]
Emphysema	100.0% [59.0%, 100.0%]	100.0% [83.9%, 100.0%]	1.000 [1.000, 1.000]

Fibrosis	100.0% [89.7%, 100.0%]	95.2% [86.5%, 99.0%]	0.963 [0.912, 1.000]
Infiltration	93.3% [68.1%, 99.8%]	95.2% [86.7%, 99.0%]	0.954 [0.900, 0.992]
Lung Lesion	N/A*	87.5% [47.3%, 99.7%]	N/A*
Lung Opacity	100.0% [2.5%, 100.0%]	94.7% [82.3%, 99.4%]	1.000 [1.000, 1.000]
Pleural Thickening	100.0% [2.5%, 100.0%]	95.0% [75.1%, 99.9%]	0.950 [0.842, 1.000]

In the 73 studies that had pneumothorax with combination of pleural effusion co-existing, performance accuracy of detecting Pneumothorax was maintained at: AUC of 0.982 (95% CI: [0.957, 0.997]).

Justification of Sub-Group Performance (Pneumothorax):
In the overall study population the device met all acceptance criteria across the full 95% confidence interval. As with pleural effusion, the sub-threshold subgroup confidence-interval lower bounds, and the small number of sub-0.95 AUC point estimates were observed. The majority arise from small positive or normal case counts in the limiting subgroups for example the KODAK (2 positive studies), Canon, SIEMENS, Samsung and GE Healthcare manufacturers; the small pneumothorax (<3 cm) and bilateral size and laterality categories; and the us_east, us_southwest and us_southeast regions (the last with a single positive study) where the point estimates meet the criteria and the wide intervals reflect sampling uncertainty rather than a performance deficit.

The Black race subgroup (n=17) shows an AUC point estimate (0.850) for pneumothorax; this is statistically fragile rather than indicative of a true demographic disparity. Its confidence interval ([0.591, 1.000]) is extremely wide and fully overlaps those of the better-powered White (0.982 [0.963, 0.996]) and Unknown (0.981 [0.967, 0.992]) cohorts, and the same 17-study cohort shows concordant, criteria-meeting performance for pleural effusion (AUC 0.967, sensitivity 100%, specificity 91.7%) a cross-pathology pattern inconsistent with a systematic, model-level demographic bias, which would be expected to manifest across both pathologies.

The remaining marginally sub-0.95 AUC point estimates in adequately powered subgroups (e.g., the us_telerad region, the Consolidation confounder cohort, and the imaging-artifact and implanted-device cohorts) are confined to specificity and the false-positive rate, are explained by acquisition-context and radiographic-overlap effects acting on the non-diseased population, and are accompanied by preserved high sensitivity.

With regards to device performance time, NEUROCAREAI INC assessed the performance time of CXRDetectAI across all three deployment pipelines on the complete 839 performance test dataset. The mean performance time for the Cloud Pipeline was 9.32 seconds (95% CI: 9.20, 9.44) for pleural effusion and 9.19 seconds (95% CI: 9.07, 9.32) for pneumothorax. The Edge Pipeline achieved 4.86 seconds (95% CI: 4.80, 4.92) for pleural effusion and 4.78 seconds (95% CI: 4.71, 4.85) for pneumothorax. The ConnectAI App pipeline achieved 21.65 seconds (95% CI: 21.42, 21.88) for pleural effusion and 21.45 seconds (95% CI: 21.22, 21.69) for pneumothorax. The predicate device Lunit INSIGHT CXR Triage reported performance times of 20.76 seconds (95% CI: 20.23, 21.28) for pleural effusion and 20.45 seconds (95% CI: 19.99, 20.92) for pneumothorax. CXRDetectAI demonstrated comparable or superior performance time across all three deployment configurations, confirming that specialists have the opportunity to become involved in the clinical workflow early with prioritization from the CXRDetectAI software.

Conclusion:
The comparison of the subject and predicate devices in the table, along with the software and performance testing presented above, demonstrates that CXRDetectAI is substantially equivalent to the predicate device, Lunit INSIGHT CXR Triage. Like the predicate, CXRDetectAI is a software-only device and is designed to be as safe and effective. It shares the same intended users, similar technological characteristics, principles of operation and indications for use. The minor differences do not introduce new safety concerns, nor do they impact the device's safety and effectiveness when used as labeled. Both devices function in parallel with the standard of care workflow. Performance testing confirms that CXRDetectAI operates as intended, and software and clinical testing further support that it meets all defined software requirements. Hence the subject device CXRDetectAI is substantially equivalent to the predicate device Lunit INSIGHT CXR Triage.