VUNO Inc.
% Priscilla Chung
RA Associate
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, California 92612

November 15, 2024

Re: K241439
Trade/Device Name: VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: May 21, 2024
Received: October 9, 2024

Dear Priscilla Chung:

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241439

Device Name

VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage

Indications for Use *(Describe)*

VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link 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, VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage does not send a proactive alert directly to the appropriately trained medical specialists. VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

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

(K241439)

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. **Date:** 10/08/2024

2. **Applicant / Submitter**

VUNO Inc.
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Seoul, 06541, Republic of Korea
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3. **U.S. Designated Agent**

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. **Trade/Proprietary Name:**

VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage

5. **Common Name:**

Radiological Computer Assisted Prioritization Software for Lesions

6. **Classification:**

21 CFR 892.2080
QFM (Class II)
Radiological computer aided triage and notification software

7. **Device Description:**

VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is an automated computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pleural effusion and pneumothorax. It is based on an artificial intelligence

analysis model, specifically a convolutional neural network (CNN), which employs deep learning technology to learn features from data.
The training data is sourced from 4 distinct sites of South Korea and India data provider, including medical imaging centers, data partners, and medical hospitals, and over 13 different modality manufacturers such as GE, Philps, FUJI, Canon, Samsung, SIEMENS, etc.
A "locked" algorithm is used, and the same input gives the same results every time.
The software receives an image of a frontal chest radiograph and automatically analyzes it for the presence of pre-specified critical findings. If any findings are suspected, the image is flagged, and a passive notification is provided to the user. Subsequently, trained radiologists or healthcare professionals should make the final decision which is the standard of care at present. A user interface is provided for visualization, displaying the loaded image and any detected findings.
The data can be transmitted from Picture Archive and Communications Systems (PACS) using the DICOM protocol.

8. Indication for use:

VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link 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, VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage does not send a proactive alert directly to the appropriately trained medical specialists. VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

9. Predicate Device:

qXR-PTX-PE (K230899) by Qure.ai Technologies

10. Substantial Equivalence:

Comparison Table

The subject device is substantially equivalent to the following predicate device:

- 510(k) number: K230899
- Device name: qXR-PTX-PE

	Subject Device	Predicate Device
Device Name	VUNO Med-Chest X-ray Triage/ VUNO Med-CXR Link Triage	qXR-PTX-PE
510(k) Number	K241439	K230899
Regulation	21 CFR 892.2080	21 CFR 892.2080
Regulation Description	Radiological computer aided triage and notification software	Radiological computer aided triage and notification software
Product Code	QFM	QFM
Device Type	Radiological Computer-Assisted Prioritization Software For Lesions	Radiological Computer-Assisted Prioritization Software For Lesions
Manufacturer	VUNO Inc.	Qure.ai Technologies
Intended use/ Indications for Use	VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link 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, VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage does not send a proactive alert directly to the appropriately trained medical specialists. VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical	qXR-PTX-PE is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). qXR-PTX-PE 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, qXR-PTX-PE does not send a proactive alert directly to the appropriately trained medical specialists. qXR-PTXPE is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a standalone basis for clinical decision-making.

	Subject Device	Predicate Device
	decision-making.	
Intended User	Trained radiologists and healthcare professionals	Radiologists, clinicians, and other appropriately trained medical specialists qualified to read chest radiographs
Modality	Chest X-ray	Chest X-ray
Target Clinical Conditions	Pneumothorax, Pleural effusion on Chest/Lung Frontal Chest X-rays	Pneumothorax, Pleural effusion on Chest/Lung Frontal Chest X-rays
Algorithm for pre-specified critical findings detection	VUNO Med-Chest X-ray Triage/ VUNO Med-CXR Link Triage uses an AI algorithm to detect pneumothorax and pleural effusion on chest X-ray images. VUNO Med-Chest X-ray Triage/ VUNO Med-CXR Link Triage uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.	qXR-PTX-PE uses an AI algorithm to detect pneumothorax and pleural effusion on chest X-ray images. qXR-PTX-PE uses a vendor agnostic algorithm compatible with DICOM chest X-ray images.
Notification only/ Parallel workflow	Yes	Yes
Input format	DICOM, JPG, PNG	DICOM
Device output in case of positive detection	When deployed on other radiological imaging equipment, VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage will automatically run after image acquisition to perform triage. It displays the analysis result through the worklist interface of PACS/workstation. No markup of the conditions will be done on the original image. Secondary capture of the device will indicate the presence of findings suspicious of pneumothorax or pleural effusion. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems) a passive notification is generated.	When deployed on other radiological imaging equipment, qXR-PTX-PE will automatically run after image acquisition to perform triage. It displays the analysis result through the worklist interface of PACS/workstation. No markup of the conditions will be done on the original image. Secondary capture of the device will indicate the presence of findings suspicious of pneumothorax or pleural effusion. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems) a passive notification is generated.
Notification (i.e., recipient,	Passive notification. Images with suspicion of pneumothorax and/or	Passive notification. Images with suspicion of pneumothorax and/or

	Subject Device	Predicate Device
timing and means of notification)	pleural effusion are flagged in PACS/workstation/DICOM viewer.	pleural effusion are flagged in PACS/workstation/DICOM viewer.
Where generated results(i.e., DICOM files) are stored	PACS/Workstation/DICOM viewer	PACS/Workstation/DICOM viewer
Performance level - Timing of notification	The average time taken for the notification to travel from VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage to the point at which the result is displayed in the destination Picture Archiving and Communication System(PACS) or workstation/digital radiographic processing system (ex. digital radiography, digital X-ray system etc.) is below 10 seconds.	The average time taken for the notification to travel from qXR-PTX-PE to the point at which the result is displayed in the destination Picture Archiving and Communication System(PACS) or workstation/digital radiographic processing system (ex. digital radiography, digital X-ray system etc.) is 10 seconds.
Performance level - Accuracy of classification	**Pneumothorax** ROC AUC > 0.95 AUC: 0.9883 (95% CI: [0.9815, 0.9939]) Sensitivity 95.45 % (95% CI: [92.01, 97.71]) Specificity 96.41% (95% CI: [94.32, 97.90]) **Pleural Effusion** ROC AUC > 0.95 AUC: 0.9900 (95% CI: [0.9863, 0.9932]) Sensitivity 96.53% (95% CI: [94.24, 98.09]) Specificity 95.11% (95% CI: [93.37, 96.50])	**Pneumothorax** ROC AUC > 0.95 AUC: 0.9894 (95% CI: [0.9829, 0.9980]) Sensitivity 94.53% (95% CI: [90.42, 97.24]) Specificity 96.36% (95% CI: [94.07, 97.95]) **Pleural Effusion** ROC AUC > 0.95 AUC: 0.989 (95% CI: [0.9847, 0.9944]) Sensitivity 96.22% (95% CI: [93.62, 97.97]) Specificity 94.90% (95% CI: [93.04, 96.39])

Substantial Equivalence Discussion

The comparison table shows the description of the subject device and predicate device in each aspect. The comparison rationale and gap between the subject device and the predicate device are provided below.

- Indications for use

The indications for use are the same. Both are intended to detect presence of critical findings(pleural effusion and /or pneumothorax).
The intended user, modality, and target clinical condition are the same as the predicate device.

- Algorithm for pre-specified critical findings detection
  Both devices use AI algorithm to detect findings.
  As referred to in the literature, the predicate device uses a series of convolutional neural networks(CNNs) trained to identify different abnormalities on frontal CXRs. The algorithm first resizes and normalizes CXRs to decrease variations in the acquisition process, then applies modifications in either densenet or resnet network architectures to separate CXRs from radiographs of other anatomies. Subsequently, multiple networks, including densenets and resnets, are applied for individual CXR findings.[1]
  Similarly, the subject device uses convolutional neural networks(CNNs) to analyze pre-specified findings. The algorithm firstly resizes and normalizes the image through a pre-processing step, then proceeds through the classification model to detect findings.
  The algorithm used for both predicate and subject device is equivalent, although there may be minor differences. However, the accuracy of the output is verified through performance test.

- Notification only/Parallel workflow
  Both devices are used for notification/triage. The output of device is not directly used to the diagnosis, and the final decision should be performed by user. It is used parallel to the standard workflow.

- Input format
  The predicate device generates DICOM format image, while the subject device generates DICOM, JPG, and PNG format.
  Both devices utilize the DICOM format, which is the international standard for medical images and related information. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use.
  Additionally, for use convenience, the subject device accepts JPG and PNG format. When user uploads the image, DICOM, JPG or PNG format is acceptable. This functionality is verified and validated through software testing.
  The input format is considered to be the equivalent.

- Device output in case of positive detection
  Both devices provide same output in case of positive detection.
  There is no markup of the conditions, and the secondary capture of result will be sent to the worklist interface of PACS or workstation. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems) a passive notification is generated.

- Notification (i.e., recipient, timing and means of notification)

[1] Parisa Kaviani, et al., Performance of a Chest Radiography AI Algorithm for Detection of Missed or Mislabeled Findings: A Multicenter Study, **Diagnostics 2022**, **12**(9), 2086;

Recipient, timing and means of notification is the same between subject and predicate device.
A passive notification is provided in both devices. Images with suspicion of findings(pneumothorax and/or pleural effusion) are flagged in PACS/workstation/DICOM viewer.
The performance result of notification timing is described below.

- Where generated results(i.e., DICOM files) are stored
  The generated results are stored in the PACS/Workstation/DICOM viewer which is the same between the subject and predicated device.

- Performance level – Timing of notification
  The timing of notification performance is equivalent.
  The average time for displaying results was 10 seconds for the predicate device, and 7.86 seconds for the subject device.

- Performance level – Accuracy of classification
  The accuracy of classification performance is equivalent. Both Pneumothorax and Pleural Effusion exceed ROC AUC 0.95.

  Clinical studies were conducted on retrospectively collected chest X-rays to evaluate the performance of subject device for triaging of pneumothorax and pleural effusion.

  The subgroup analysis was performed to demonstrate the robustness of the device performance under diverse conditions. Every subgroup, age, gender, view position, dataset, and vendor outperformed the target performance.

- Safety
  The risks associated with the use of a medical device should be established, implemented, documented, and maintained to ensure the device's safety. The risk management process complies with ISO 14971:2019. Through risk analysis, the device is determined to be safe and beneficial.

VUNO Med-Chest X-ray Triage/VUNO Med-CXR Link Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax).
The intended use and other aspects are considered to be the same as the predicate device. However, the algorithm used for data analysis might have difference. Although both use convolutional neural networks(CNNs), which are one of the deep learning models, the detailed mechanisms are different.
Despite the minor differences, the subject device shows reliable output in the performance test. And an analysis results are not intended to be used on a stand-alone basis for clinical decision-making.
In conclusion, the subject device is substantially equivalent to the predicate device, and no additional risks are presented in the perspective of safety and effectiveness.

11. Performance Data:

Software Validation

Software 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."

Performance Testing – Clinical

The accuracy of classification performance and the timing of notification are validated through clinical tests. These tests are conducted on retrospectively collected chest X-rays to evaluate the performance of the device for triaging pneumothorax and pleural effusion. Both pneumothorax and pleural effusion exceed the acceptance criteria, with ROC AUC values of 0.95.

A total dataset of 1,200 scans for pleural effusion and 716 scans for pneumothorax were used in the test dataset to evaluate the standalone performance of VUNO Med-Chest X-ray/VUNO Med-CXR Link Triage for triaging of pleural effusion and pneumothorax, in terms of classification accuracy. The test dataset is independent of the training dataset, with each sourced from a different country.
Each scan sourced from different subjects and was obtained through a general inclusion/exclusion criterion, ensuring comprehensive subgroup representation.

The dataset for pneumothorax included 716 scans (242 scans with pneumothorax and 474 scans without pneumothorax). It is sourced from various regions of the US: Midwest, West, Northeast, and South. Various demographic and medical characteristics such as gender(males and females), age(22 years and older), race/ethnicity(White, Hispanic and Latino, Black, and Asian), radiographic view position (PA and AP), and vendors(Siemens, Konica Minolta, Samsung Electronics, Canon, GE Medical Systems, Carestream Health, and Fujifilm) are considered to ensure that the device's performance is consistent across the intended population. The dataset consisted of clinical confounders that included opacities, emphysema, scarring, mediastinal widening, pleural thickening, and presence of hardware. The datasets were also obtained from diverse X-ray device vendors, such as GE, Philips, Siemens, Samsung electronics, Konica, Cannon, Fuji film, with an average exposure of 112±13 kVp (range from 49 kVp to 135 kVp) to ensure consistent performance.
The predicate device has used 613 scans (201 scans with pneumothorax and 412 scans without pneumothorax) for performance testing of pneumothorax.
The ground truth was established by 3 ABR radiologists with a minimum of 5 years of experience.

The AUC of the subject device in triaging scans with findings suspicious of pneumothorax exceeded the acceptance criteria with AUC 98.83 (95%CI, 98.15 - 99.39), Sensitivity 95.45 (92.01 - 97.71), and Specificity 96.41 (94.32 - 97.90).
The predicated device was reported as (AUC 98.94 (95% CI, 98.28 - 99.82)), Sensitivity 94.53 (90.42-97.24) and Specificity 96.36(94.07-97.95).

AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
98.83 (98.15 - 99.39)	95.45 (92.01 - 97.71)	96.41 (94.32 - 97.90)

[Table 1. Overall results of classification accuracy of Pneumothorax]

The subgroup analysis was performed to demonstrate the robustness of the device performance under diverse conditions. Every subgroup, age, gender, view position, dataset, and vendor outperformed the target performance.

Test dataset for pleural effusion included 1,200 scans (403 scans with pleural effusion and 797 scans without pleural effusion) It is sourced from various regions of the US: Midwest, West, Northeast, and South. Various demographic and medical characteristics such as gender(males and females), age(22 years and older), race/ethnicity(White, Hispanic and Latino, Black, and Asian), radiographic view position (PA and AP), and vendors(Siemens, Konica Minolta, Samsung Electronics, Canon, GE Medical Systems, Carestream Health, and Fujifilm) are considered to ensure that the device's performance is consistent across the intended population. The dataset consisted of clinical confounders that included opacities, emphysema, scarring, mediastinal widening, pleural thickening, and presence of hardware. The datasets were also obtained from diverse X-ray device vendors, such as GE, Philips, Siemens, Samsung electronics, Konica, Cannon, Fuji film, with an average exposure of 112±11 kVp (range from 49 kVp to 137 kVp) to ensure consistent performance.
The predicate device has used 1,070 scans (344 scans with pleural effusion and 726 scans without pleural effusion) for performance testing of pleural effusion.
The AUC of the subject device in triaging scans with findings suspicious of pleural effusion exceeded the acceptance criteria with AUC 99.00 (95%CI, 98.63 - 99.32), Sensitivity 96.53 (94.24 - 98.09), and Specificity 95.11 (93.37 - 96.50).
The predicated device was reported as AUC 98.90 (98.47 -99.44)), sensitivity 96.22 (93.62-97.97) and specificity 94.90 (93.04-96.39).

AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
99.00 (98.63 - 99.32)	96.53 (94.24 - 98.09)	95.11 (93.37 - 96.50)

[Table 2. Overall results of classification accuracy of Pleural effusion]

The subgroup analysis was performed to demonstrate the robustness of the device performance under diverse conditions. Every subgroup, age, gender, view position, dataset, and vendor outperformed the target performance.

The average time for displaying results was 10 seconds for the predicate device, and also below 10 seconds for the subject device.

12. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The new device does not introduce a fundamentally new scientific technology, and the device has been validated through performance test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.