Qure.ai Technologies
℅ Ayushi Mahendra
Senior Regulatory Affairs Specialist
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International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai, Maharashtra 400063
INDIA

August 22, 2023

Re: K230899
Trade/Device Name: qXR-PTX-PE
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: July 24, 2023
Received: July 24, 2023

Dear Ayushi Mahendra:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230899

Device Name
qXR-PTX-PE

Indications for Use *(Describe)*

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-PTX-PE 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

Qure.ai's qXR-PTX-PE

K230899

1 SUBMITTER

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Mumbai 400 063
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Primary Contact Person: Ayushi Mahendra
Secondary contact person: Sri Anusha Matta

Date Prepared: August 12, 2023

2 DEVICE

Name of Device:	qXR-PTX-PE
Common or Usual Name:	Radiological Computer Assisted Prioritization Software for Lesions
Classification Name:	Radiological Computer Aided Triage and Notification Software
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2080
Product Code:	QFM

3 PREDICATE DEVICE

Name of Device:	Lunit INSIGHT CXR Triage
Manufacturer:	Lunit Inc.
510(k) Number:	K211733

4 INTENDED USE / INDICATIONS FOR USE:

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-PTX-PE 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.

5 DEVICE DESCRIPTION

qXR-PTX-PE is a radiological computer aided triage and notification software that analyses adult frontal (AP or PA views) CXR images for the presence of pre-specified suspected target conditions (pleural effusion and/or pneumothorax). The algorithm was trained on training data from across the world. The training dataset consisted of 74% of the data from India, 20.04% from the EU, 3.9% from the US, 1.4% from Brazil and 0.63% from Vietnam. The input for qXR-PTX-PE is a frontal chest X-ray (AP and PA view) in digital imaging and communications in medicine (DICOM) format

Chest X-rays are sent to qXR-PTX-PE by the means of transmission functions within the user's image storage system (e.g., Picture Archiving and Communication System (PACS)) or other radiological imaging equipment (e.g., X-ray systems) and processed by the qXR-PTX-PE for analysis. Following receipt of chest radiographs, the software device automatically analyses each image to detect features suggestive of pneumothorax and/or pleural effusion.

This would allow the appropriately trained medical specialists to group suspicious exams together that may potentially benefit for their prioritization. Chest radiographs without the suspicious findings are placed in the worklist for routine review, which is the standard of care at present. A secondary capture is available for the information on presence of the suspicious findings.

qXR-PTX-PE does not provide any proactive alerts. qXR-PTX-PE 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.

6 COMPARISON OF THE PREDICATE DEVICE

qXR-PTX-PE is technologically similar to the predicate device, Lunit INSIGHT CXR Triage in regards to intended use and technological characteristics. Both are radiological computer-assisted triage and notification software intended to read chest X-rays for the presence of pre-specified target conditions (pneumothorax and pleural effusion). The algorithms function similarly and with the same purpose of workflow notification. There are no notable technological differences between the subject and predicate devices.

In terms of establishing substantial equivalence, the subject and predicate device have the same intended use, as an image processing tool that triages images for features suggestive of critical findings and produces case-level output. The indications for use proposed for the subject device are similar to those of the predicate device.

Table 1 Comparison between qXR-PTX-PE and the Predicate Device

	Predicate Device **Lunit INSIGHT CXR Triage**	**Subject Device** **qXR-PTX-PE**
Device Name	Lunit INSIGHT CXR Triage	qXR-PTX-PE
510(k) Number	K211733	
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	Lunit Inc.	Qure.ai Technologies
Intended use / Indications for Use	Lunit INSIGHT CXR 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 effusions and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and produce 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, Lunight Insight CXR triage does not send a proactive alert directly to 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 standalone basis for clinical decision-making.	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-PTX-PE 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
Intended User	Appropriately trained medical specialists who are qualified to interpret chest radiographs.	Radiologists, clinicians, and other appropriately trained medical specialists qualified to read chest radiographs
Modality	Chest X-ray	Chest X-ray

	Predicate Device **Lunit INSIGHT CXR Triage**	**Subject Device** **qXR-PTX-PE**
Target clinical conditions	Pleural effusion, Pneumothorax on Chest/Lung Frontal Chest X-ray	Pneumothorax, Pleural effusion on Chest/Lung Frontal Chest X-rays
Algorithm for pre-specified critical findings detection	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	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	DICOM
Device output in case of positive detection	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. The on device 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	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, 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 pneumothorax and/or pleural effusion are flagged in PACS/workstation/DICOM viewer.
Where generated results (i.e., DICOM files) are stored	PACS/Workstation	PACS/Workstation/DICOM viewer

	Predicate Device Lunit INSIGHT CXR Triage	Subject Device qXR-PTX-PE
Performance metrics of the predicate device and qXR-PTX-PE		
Performance level – Timing of notification	The average time taken for the notification to travel from the Lunit INSIGHT CXR Triage to the point at which the result is displayed in the destination PACS/RIS/EPR worklist is 14.66 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	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])	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])

7 TESTING

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." The software for this device has a Moderate level of concern.

Performance Testing – Clinical

The performance of qXR-PTX-PE was validated by clinical tests. All the safety parameters of the device were verified in accordance with the software specifications and applicable performance standards and met the acceptance criteria (Device shows > 95% AUC) (passed), demonstrating that the software fulfills all its requirement specifications.

Clinical studies were conducted on retrospectively collected Chest X-rays to evaluate the performance of qXR-PTX-PE for triaging of pneumothorax and pleural effusion.

The study for pneumothorax included 613 scans (201 scans with pneumothorax and 412 scans without pneumothorax) from various parts of the US. The dataset was obtained from various hospitals across the US in order to generate evidence on the device function in various subgroups. A data collection protocol was set in place to ensure that there were sufficient numbers of important subgroups. The protocol specifies the inclusion and exclusion criteria and the expected numbers of cases and controls to be included. The dataset consisted of 289 males, 287 females and 37 were without this information available. The cases were aged from 22 years to above 85 years. The dataset was obtained from various hospitals across the US (179 from the Midwest, 152 from the West 125 from the Northeast and 12 from the South, region for 145 were not known) in order to generate evidence on the device function in various subgroups. The dataset consisted of clinical confounders that included opacities, presence of hardware, emphysema, scarring, mediastinal widening and pleural thickening. The dataset was also obtained from various X-ray device manufacturers to ensure consistent performance.

The algorithm was trained on training data from across the world. The training dataset consisted of 74% of the data from India, 20.04% from the EU, 3.9% from the US, 1.4% from Brazil and 0.63% from Vietnam. The test set was obtained from sites that were different from the training data sites and therefore this ensured the independence of the test data from training data.

The ground truth was established by 3 ABR thoracic radiologists with a minimum of 10 years of experience. The AUC of the device in triaging scans with findings suspicious of pneumothorax exceeded the success criteria with (AUC 98.94 95% CI (98.28 - 99.82)), Sensitivity 94.53 (90.42-97.24) and Specificity 96.36 (94.07-97.95). The predicate Lunit INSIGHT CXR Triage's performance 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).

Table 2 Overall Results of Accuracy Testing of qXR-PTX-PE for Pneumothorax

AUC (95% CI)	**Sensitivity (95% CI), TP/P**	**Specificity (95% CI), TN/N**
98.94 (98.28 - 99.82)	94.53 (90.42-97.24), 190/201	96.36 (94.07-97.95), 397/412

The device's generalizability was ensured by performing subgroup analyses. The results for pneumothorax were consistent in both genders and the AUC was 98.67 (97.63-100) in male, 99.3(98.64-100) in female. An AUC of 92.47(84.95-100) was observed in the scans with unknown gender. The device's results were also found to be consistent in a wide range of ages: with AUC of 99.12 (98.34-100) in the 22-44 age group, 99.17 (98.37-100) in the 45-64 age group, 98.69 (97.61-100) in the 65-84 age group and 98.62 (97.25-100.00) in the 85 or greather age group age group.

The study for pleural effusion included 1070 scans (344 scans with pleural effusion and 726 scans without pleural effusion) from various parts of the US. A data collection protocol was set in place to ensure that there were sufficient numbers of important subgroups. The protocol specifies the inclusion and exclusion criteria and the expected numbers of cases and controls to be included. There were 498 scans from females and 551 from males, 21 samples did not have this information available. The ages ranged from 22 years to greater than 85 years. The samples were from various parts of the US (278 from the Midwest, 213 from the Northeast, 6 from the South, 308 from the West. For 265, this information was not known). The dataset consisted of clinical confounders that included opacities, presence of hardware, emphysema, scarring, mediastinal widening and pleural thickening. The dataset was also obtained from various X-ray device manufacturers to ensure consistent performance. The algorithm was trained on training data from across the world. The training dataset consisted of 74% of the data from India, 20.04% from the EU, 3.9%

from the US, 1.4% from Brazil and 0.63% from Vietnam. The test set was obtained from sites that were different from the training data sites and therefore this ensured the independence of the test data from training data.

The ground truth was established by 3 ABR thoracic radiologists with a minimum of 10 years of experience. The AUC of the device in triaging scans with findings suspicious of pleural effusion with AUC 98.90 (98.47 - 99.44)), sensitivity 96.22 (93.62-97.97) and specificity 94.90 (93.04-96.39). The predicate, Lunit INSIGHT CXR Triage, reported a performance of 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).

Table 3 Overall Results of Accuracy Testing of qXR-PTX-PE for Pleural Effusion

AUC (95% CI)	**Sensitivity (95% CI), TP/P**	**Specificity (95% CI), TN/N**
98.90 (98.47 - 99.44)	96.22 (93.62-97.97), 331/344	94.90(93.04- 96.39), 689/726

The device's generalizability for triaging scans with pleural effusion was ensured by performing subgroup analyses. The results for pleural effusion were consistent in both genders and the AUC was 98.73 (98.00-99.74) in female, 99.11(98.62-99.72) in male. An AUC of 96.3(92.59-100) was observed in the scans with unknown gender. The device's results were also found to be consistent in a wide range of ages: with AUC of 99.27 (98.56-100) in the 22-44 age group, 98.1 (96.83-99.95) in the 45-64 age group, 98.78 (98.09-99.62) in the 65-84 age group and 99.2 (98.39-100.00) in the 85 or greater age group. The device's performance time was also assessed and for qXR-PTX-PE. It was the time time to analyze the study and send the notification to the worklist. The performance time averaged at 10s. This is comparable to the performance of the predicate performance of 14.66s. This is also comparable to other commercially cleared products with the similar intended use.

8 CONCLUSION

The comparison in Table 1 and the software and performance testing presented above demonstrate that the qXR-PTX-PE device is substantially equivalent to the predicate device. The qXR-PTX-PE is a software only device, similar to the predicate (Lunit INSIGHT CXR Triage). It is as safe and effective as the predicate device. The qXR-PTX-PE has the same intended users and similar indications, technological characteristics, and principles of operation as the predicate device. There are no differences in the indications, therefore there no is risk of its safety and effectiveness being affected when used as labelled. Both devices operate in parallel to the standard of care workflow. The performance testing demonstrates that the qXR-PTX-PE performs as intended and is therefore substantially equivalent to the predicate. Software and Clinical testing supports that the device performs in according with the device requirements.