December 22, 2023

Qure.ai Technologies
℅ Sri Anusha Matta
Senior Regulatory Affairs Manager
Level 7, Commerz II, International Business Park
Oberoi Garden City, Goregaon(E)
Mumbai, Maharashtra 400063
INDIA

Re: K231805
Trade/Device Name: qXR-LN
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: June 19, 2023
Received: June 20, 2023

Dear Sri Anusha Matta:

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.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K231805

Device Name
qXR-LN

Indications for Use *(Describe)*
The qXR-LN (qXR_Lung_nodule) is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 6 to 30 mm in size. The device is intended to be used in the incidental adult population. It is designed to aid the physician to review the frontal (AP/PA) chest radiographs of adults acquired on digital radiographic systems as a second reader and be used with any DICOM viewer or PACS . qXR-LN provides adjunctive information only and is not a substitute for the original chest radiographic image.

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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-LN

1 SUBMITTER

Qure.ai Technologies
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Mumbai 400 063
Phone: +91-9768123013
Primary Contact Person: Sri Anusha Matta
Secondary contact person: Bunty Kundnani

Date Prepared: June 16, 2023

2 DEVICE

Name of Device:	qXR-LN
Common or Usual Name:	Analyzer, Medical Image
Classification Name:	Medical image analyzer
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2070
Product Code:	MYN

3 PREDICATE DEVICE

Name of Device:	Auto Lung Nodule Detection
Manufacturer:	Samsung Electronics Co., Ltd
510(k) Number:	K201560

4 INTENDED USE / INDICATIONS FOR USE:

The qXR-LN (qXR_Lung_nodule) is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 6 to 30 mm in size. The device is intended to be used in the incidental adult population. It is designed to aid the physician to review the frontal (AP/PA) chest

radiographs of adults acquired on digital radiographic systems as a second reader and be used with any DICOM viewer or PACS . qXR-LN provides adjunctive information only and is not a substitute for the original chest radiographic image.

5 DEVICE DESCRIPTION

qXR-LN is a Computer-Aided Detection (CADe) device that is designed to perform CAD processing in frontal (PA or AP view) Chest X-ray images for indication of locations for high nodule probability, which has an effective detection size from 6 mm to 30 mm. The device is intended to be a secondary aid to the qualified intended user to identify incidental pulmonary lung nodules chest x-ray images.

The device utilizes a deep learning algorithm. The qXR-LN was trained on a large and diverse dataset of 2.5million scans from 5 countries across the world. The training dataset was from more than 25 manufacturers.

Chest X-rays are sent to qXR-LN 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-LN to detect and localise lung nodules. Following receipt of chest radiographs, the software device automatically analyses each image to detect and localise lung nodules.

qXR-LN receives chest x-ray images in digital imaging and communications in medicine (DICOM) as input. The qXR-LN device produces DICOM format outputs that enable users to view the presence and location of lung nodules.

This device is intended to aid the intended user in review of chest x-rays and detect and localise lung nodules as a secondary reader. 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-LN is technologically similar to the predicate device, Samsung Electronics Auto Lung Nodule Detection in regard to the intended use and technological characteristics. Both are medical image analysers intended to read chest X-rays to detect and localise lung nodules. The algorithms function similarly and with the same purpose of detection and localization of lung nodules. There are minor technological differences between the subject and predicate devices. Samsung Auto Lung Nodule Detection detects and marks nodules sized 10-30mm, whereas, qXR-LN can detect and mark nodules sized 6-30mm. The device is intended to be used in the incidental adult population. Performance testing demonstrates that even with the difference in nodule size detection the device performance is substantially equivalently to the predicate device. The intended users of Samsung Auto Lung Nodule Detection are physicians, whereas, the intended users of the qXR-LN are radiologists, emergency room physicians or pulmonologists. The difference in intended users does not raise different questions of safety or effectiveness.

In terms of establishing substantial equivalence, the subject and predicate device have the same intended use, as a medical image analyser that detects and localises lung nodules and produces case-level output.

Table 1 Comparison between qXR-LN and the Predicate Device

		Predicate Device **Auto Lung Nodule Detection**	**Subject Device** **qXR-LN**
Device Name		Auto Lung Nodule Detection	qXR-LN
510(k) Number		K201560	K231805
Regulation		21 CFR 892.2070	21 CFR 892.2070
Regulation Description		Medical Image Analyser	Medical Image Analyser
Product Code		MYN	MYN
Device type		Medical Image Analyser	Medical Image Analyser
Manufacturer		Samsung Electronics Co., Ltd	Qure.ai Technologies
Intended use / Indications for Use		The Auto Lung Nodule Detection is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 10 to 30 mm in size. It is designed to aid the physician to review the PA chest radiographs of adults as a second reader and be used as part of S-Station, which is operation software installed on Samsung Digital X-ray Imaging systems. Auto Lung Nodule Detection cannot be used on the patients who have lung lesions other than abnormal nodules.	The qXR-LN (qXR_Lung_nodule) is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 6 to 30 mm in size. The device is intended to be used in the incidental adult population. It is designed to aid the physician to review the frontal (AP/PA) chest radiographs of adults acquired on digital radiographic systems as a second reader and be used with any DICOM viewer or PACS . qXR-LN provides adjunctive information only and is not a substitute for the original chest radiographic image.
Intended User		Physicians.	Radiologists, emergency room physicians or pulmonologists who regularly review chest X-rays as part of their daily practice.
Modality		Chest X-ray	Chest X-ray
Target clinical conditions		Lung Nodules on PAview Chest X-rays	Lung Nodules on PA/AP view Chest X-rays
Technology		Machine learning	Deep/Machine Learning
Input format		DICOM	DICOM
Output	**Type**	ROI marked on the duplicated input image.	ROI marked on the duplicated input image

	Predicate Device Auto Lung Nodule Detection	Subject Device qXR-LN
Performance Metrics		
Performance metrics used	Sensitivity, FPPI and JAFROC were calculated	Sensitivity, FPPI and AFROC were calculated
	Nodule level sensitivity 80.69%	Nodule level sensitivity 84.10 (77.97-97.24)
	JAFROC (aided – unaided) 7.8 (p=0.0003) FPPI (aided – unaided) +0.019 Nodule level Sensitivity (aided-unaided) 10.8	AFROC (aided - unaided) 7.62 ($p < 1 \times 10^{-5}$) FPPI (aided – unaided) -0.0078 Nodule level Sensitivity (aided – unaided) 11.96

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

A standalone study to assess device performance was conducted. These scans were obtained from 8 states (Ohio, New York, South Carolina, Iowa, Wisconsin, Texas, Oklahoma and Maryland) and 40 sites (each state had multiple sites) across the US. There were 55.48% females. Most scans (90.92%) were between 22 and 85 years of age. 31.43% scans were obtained from portable X-ray machines. The scans were sourced from more than 10 manufacturers. The data also consisted of commonly existing confounding conditions (mimickers, hardware or others). The standalone study was performed to compare qXR-LN's performance against a ground truth determined by 5 ABR certified ground truthers. They read the Chest X-rays with the accompanying CT scans and reports and the ground truth was based on the nodules visible on the Chest X-ray. qXR-LN achieved a nodule-level sensitivity of 84.1% which we believe is substantially equivalent to the predicate's performance. The overall FPPI was 0.18 (0.14 - 0.22). As secondary metrics, scan level analyses were performed. qXR-LN achieved a scan level AUC of 94.51 (92.64 - 96.66). Sensitivity of 93.83 (88.94 – 97) and specificity of 81.09 (76.30 – 85) was achieved. Subgroup analyses was performed and presented for relevant subgroups including age, gender, race, nodule characteristics, manufacturer, location of nodule, scan view and confounders.

A fully crossed multi-case, multi-reader, retrospectively study design was utilized. The MRMC study was conducted in a sequential study design as a second read aid. An image viewer without or with AI

algorithms for lung nodule detection was used for chest X-ray scans. The ground truth was previously established by board-certified radiologists in the standalone study.

The readers consisted of radiologists, pulmonologists and ER physicians who had experience of less 3, 3-7 and more than 7 years.

The multi-reader multi-case demonstrated that aided readers performance for lung nodule detection was improved with statistical significance compared to unaided. We have performed subgroup analyses for several key subgroups to demonstrate generalizability.

Table 2 Performance of readers aided vs unaided by qXR-LN

Modality	AFROC Estimate (95% CI)	AFROC (aided-unaided)	P - Value
Aided	0.8095 (0.7695-0.8494)	0.07621 (0.0497 – 0.1026)	$P < 1 \times 10^{-5}$
Unaided	0.7333 (0.6892-0.7774)		

As secondary metrics, AUC and nodule level sensitivity were estimated. The AUC of the readers improved by an estimate of 0.0697 (0.442 – 0.0953) and this result was significant. qXR-LN indicated 11.96% improvement for nodule level sensitivity. Subgroup analyses was performed and presented for relevant subgroups including age, gender, race, nodule characteristics, manufacturer, reader type, reader experience,location of nodule, scan view and confounders.

8 CONCLUSION

The comparison in Table 1 and the software and performance testing presented above demonstrate that the qXR-LN device is substantially equivalent to the predicate device. The qXR-LN is a software only device, similar to the predicate (Samsung Auto Lung Nodule Detection). The qXR-LN has similar indications, technological characteristics, and principles of operation as the predicate device. There are minor technological differences between the subject and predicate devices. Samsung Auto Lung Nodule Detection detects and marks nodules sized 10-30mm, whereas, qXR-LN can detect and mark nodules sized 6 mm to 30 mm. The qXR-LN device can be used to detect and localize smaller nodules than the predicate and the performance of qXR-LN has been demonstrated. The intended users of Samsung Auto Lung Nodule Detection are physicians, whereas, the intended users of the qXR-LN are radiologists, emergency room physicians or pulmonologists. This does not pose any additional risks. Both devices operate as second reads in the standard workflow. The performance testing demonstrates that the qXR-LN device 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.