Qure.ai Technologies
℅ Bunty Kundnani
Head of Regulatory Affairs
Level 7, Commerz II,
International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai, Maharashtra 400063
INDIA

December 21, 2021

Re: K212690
Trade/Device Name: qXR-BT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: November 22, 2021
Received: November 24, 2021

Dear Bunty Kundnani:

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 and Part 809); 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,

for
Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K212690

Device Name
qXR-BT

Indications for Use *(Describe)*
The qXR-BT device is intended to generate a secondary digital chest X-ray image that facilitates confirmation of the position of a breathing tube and an anatomical landmark on adult chest X-rays. This device is intended for use by licensed physicians who are trained in the evaluation of breathing tube placement on chest X-rays. The qXR-BT image provides adjunctive information and is not a substitute for the original PA/AP image.

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-BT

1 SUBMITTER

Qure.ai Technologies
Level 7, Commerz II,
International Business Park
Oberoi Garden City, Goregaon (E),
Mumbai 400 063
Phone: +91-9768123013
Contact Person: Bunty Kundnani

Date Prepared: November 22, 2021

2 DEVICE

Name of Device:	qXR-BT
Common or Usual Name:	Automated Radiological Image Processing Software
Classification Name:	Medical image management and processing system
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050
Product Code:	QIH

3 PREDICATE DEVICE

Name of Device:	ClearRead+Confirm Image Processing System
Manufacturer:	Riverain Technologies LLC
510(k) Number:	K123526

4 INTENDED USE / INDICATIONS FOR USE:

The qXR-BT device is intended to generate a secondary digital chest X-ray image that facilitates confirmation of the position of a breathing tube and an anatomical landmark on adult chest X-rays. This device is intended for use by licensed physicians who are trained in the evaluation of breathing tube placement on chest X-rays. The qXR-BT image provides adjunctive information and is not a substitute for the original PA/AP image.

5 DEVICE DESCRIPTION

qXR-BT is a standalone image analysis software used during the review of digital chest radiographic images, intended to facilitate determining the position of tip of the breathing tube relative to the carina. Standard of care medical imaging workflows are well established, and include pre-existing software components such as a PACS, DICOM viewer and imaging worklist; qXR-BT is designed to integrate with these components.

X-rays are sent to qXR-BT by means of transmission functions within the user's PACS system. Upon completion of processing, the qXR-BT device returns results to the user's PACS or other user-specified radiology software system or database.

The input to the qXR-BT device is a chest X-ray (AP and PA, referred to as frontal) in digital imaging and communications in medicine (DICOM) format.

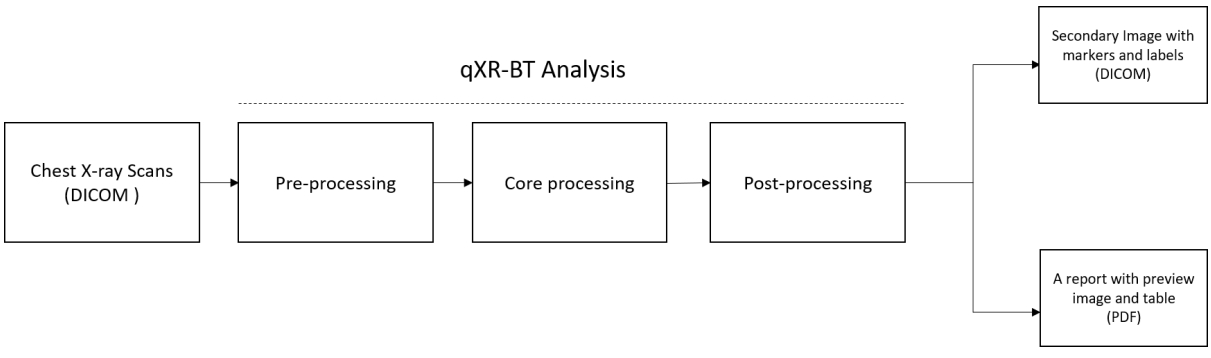
The qXR-BT device produces PDF and DICOM format outputs that enable users to view the position of a breathing tube and an anatomical landmark (carina).

The PDF format output contains preview images that show segmented structures outlined with a textual report describing the structures detected. The text report is restricted to the presence or absence of the breathing tubes and the carina as detected by the software device.

The DICOM format output consists of a single complete additional DICOM series for each input scan. This DICOM output contains labeled overlays indicating the location and extent of the segmentable structures, suitable for viewing in the PACS or radiology viewer.

The qXR-BT analysis module consists of a set of pre-trained convolutional neural networks (CNNs), that form the core processing component shown in **Figure 1**. This core processing component is coupled with a pre-processing module to prepare input DICOMs for processing by the CNNs and a post-processing module to convert the output into visual and tabular format for users.

Figure 1: Schematic showing the design of qXR-BT device



6 COMPARISON WITH PREDICATE DEVICE

Like the potential predicate devices, qXR-BT facilitates the confirmation of placement of a medically inserted tube on chest X-rays. In terms of establishing substantial equivalence, the subject and predicate device have the same intended use, as an image processing tool that generates a secondary digital radiographic image to facilitate the confirmation of the position of

medically inserted tube. The indications for use proposed for the subject device are similar to those of the predicate device, with the primary difference being that the predicate device is intended to facilitate the confirmation of multiple types of lines, tubes, and wires, while the subject device is intended to facilitate the confirmation of only one type of tube, viz. breathing tubes.

Table 1: Comparison between qXR-BT and the Predicate Device

	Predicate Device ClearRead+Confirm (K123526)	**Subject Device** **qXR-BT**
Device Name	ClearRead+Confirm	qXR-BT
510(k) Number	K123526	K212690
Regulation	21 CFR 892.2050	21 CFR 892.2050
Regulation Description	Medical image management and processing system Formerly: Picture archiving and communications system	Medical image management and processing system
Product Code	LLZ	QIH
Device type	Radiological Image Processing System	Automated Radiological Image Processing Software
Manufacturer	Riverain Technologies	Qure.ai Technologies
Intended use / Indications for Use	*ClearRead+Confirm is intended to generate an enhanced, secondary digital radiographic image of the chest to facilitate confirmation of line/tubes. The enhanced AP or PA image of the chest provides improved visibility of lines and tubes. The ClearRead +Confirm image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians, on patients with lines and tubes and is not intended to be used on pediatric patients.*	*The qXR-BT device is intended to generate a secondary digital chest X-ray image that facilitates confirmation of the position of a breathing tube and an anatomical landmark on adult chest X-rays. This device is intended for use by licensed physicians who are trained in the evaluation of breathing tube placement on chest X-rays. The qXR-BT image provides adjunctive information and is not a substitute for the original PA/AP image.*
Modality	Digital chest radiograph	Digital chest radiograph
Input format	DICOM	DICOM

	Predicate Device ClearRead+Confirm (K123526)	**Subject Device** **qXR-BT**
Output Format	Secondary digital chest X-ray image	Secondary digital chest X-ray image and other Multiple electronic reports with localization information of segmented structures
Intended User	Physicians, radiologists and technicians	Physicians and radiologists
Hardware	No additional hardware; standalone software device that integrates with PACS through DICOM protocols	qXR-BT is standalone software deployed on-premise or on the cloud, that integrates with PACS or other hardware or software imaging platforms, including digital radiographic processing systems through DICOM protocols
Comparison of Differences between qXR-BT and the predicate device		
Types of lines and tubes	Various medically inserted tubes, lines, tubes and wires	Medically inserted breathing tubes (tracheal tubes) only
Internal algorithms used for image processing and the mechanism by which the output is displayed to the clinician	ClearRead+Confirm uses a bone suppression mechanism with overall image enhancements to improve the visibility of lines and tubes and provides no boxes or markings to the user.	qXR-BT uses pre-trained convolutional neural networks to process the images, and the device highlights the tip of the tube and the carina using markings on the secondary image.

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

Qure.ai performed standalone performance testing to test the accuracy of qXR-BT's analysis. The number of Chest X-ray images used for this performance testing was 162. Table 2 shows localization accuracy for the 2 target structures – carina and tip of breathing tube and the accuracy of distance measurement between these 2 structures. The ground truth was based on manual annotation of three radiologists from United States. For the target structures, the

standalone performance exceeded the preset acceptance criteria. The table below shows a summary of the results of performance testing.

Table 2: Overall Results of Accuracy Testing in mm

Target Structure (Number of scans)	Metric	Mean (Standard Deviation)	Median (10th - 90th percentile)	Mean (95% CI)	Success Criteria
Carina (162)	Absolute Distance	2.15 (1.25)	1.86 (0.63 - 4.05)	2.15 (1.96 – 2.35)	Upper bound of 95% CI ≤ 3mm
Tip of Breathing Tube (162)	Absolute Distance	1.97 (1.09)	1.8 (0.7 - 3.64)	1.97 (1.80 – 2.13)	Upper bound of 95% CI ≤ 3mm
Distance between tip of breathing tube and carina (162)	Absolute Error	1.98 (1.41)	1.64 (0.27 - 4.12)	1.98 (1.76 – 2.20)	Upper bound of 95% CI ≤ 6mm

CI = confidence interval

qXR-BT also passed software validation and system verification checks.

8 CONCLUSION

The comparison in Table 2 and the software and performance testing presented above demonstrate that the qXR-BT device is substantially equivalent to the predicate device.