Qure.ai Technologies
℅ Srinidhi Ragunathan
Regulatory Clinical Affairs Manager
Level 7, Commerz II, International Business Park
Oberoi Garden City, Goregaon(E)
Mumbai, Maharashtra 400063
INDIA

September 22, 2023

Re: K231149
Trade/Device Name: qXR-CTR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: August 24, 2023
Received: August 24, 2023

Dear Srinidhi Ragunathan:

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)*
K231149

Device Name
qXR-CTR

Indications for Use *(Describe)*
qXR-CTR is a deep-learning based software for use by hospitals and clinics for automated assessment of the CTR on chest X-ray (CXRs) scans.

qXR-CTR is designed to measure the ratio of the maximal transverse diameter of the heart (CD) and the maximal inner transverse diameter (TD) of the thoracic cavity and calculate the CTR value on posterior-anterior view chest view using an artificial intelligence algorithm.

The intended users of this device are physicians or licensed practitioners in healthcare institutions, such as clinics, hospitals, residential care facilities, long-term care services, and healthcare facilities.

The system is suitable for adults ≥ 22 years of age.

The device is used to aid the intended users and results are not intended to be used on a stand-alone basis for clinical decision making or otherwise preclude clinical assessment of CTR cases.

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.

510(k) SUMMARY

Qure.ai's qXR-CTR

1 SUBMITTER

Qure.ai Technologies
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International Business Park
Oberoi Garden City, Goregaon (E),
Mumbai 400 063
Phone: +91-9768123013
Primary Contact Person: Srinidhi Ragunathan
Secondary contact person: Bunty Kundnani

Date Prepared: August 23, 2023

2 DEVICE

Name of Device:	qXR-CTR
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:	EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment System
Manufacturer:	Ever Fortune.AI Co., Ltd.
510(k) Number:	K212624

4 INTENDED USE / INDICATIONS FOR USE:

qXR-CTR is a deep-learning based software for use by hospitals and clinics for automated assessment of the CTR on chest X-ray (CXRs) scans.

qXR-CTR is designed to measure the ratio of the maximal transverse diameter of the heart (CD) and the maximal inner transverse diameter (TD) of the thoracic cavity and calculate the CTR value on posterior-anterior view chest view using an artificial intelligence algorithm.

The intended users of this device are physicians or licensed practitioners in healthcare institutions, such as clinics, hospitals, residential care facilities, long-term care services, and healthcare facilities.

The system is suitable for adults ≥ 22 years of age.

The device is used to aid the intended users and results are not intended to be used on a stand-alone basis for clinical decision making or otherwise preclude clinical assessment of CTR cases.

5 DEVICE DESCRIPTION

The qXR-CTR is a non-invasive software medical device designed to be installed on the computer with specific system requirements. It is a radiological computer-assisted software system that automatically analyzes DICOM chest X-ray images in PA view and outputs the cardiac diameter, thoracic diameter, and CTR through an artificial intelligence algorithm. The structured report includes a preview of the compressed chest X-ray image with the automatically derived CTR result and annotation line, indicating the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity.

6 COMPARISON OF THE PREDICATE DEVICE

qXR-CTR is technologically similar to the predicate device, EFIA iCTR Assessment in regard to intended use and technological characteristics. Both are medical image management and processing system intended to read chest X-rays to measure target structures (cardiac and thoracic diameter). The algorithms function similarly and 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 measures anatomical structures and produces case-level output. The indications for use proposed for the subject device are similar those of the predicate device.

Table 1 Comparison between qXR-CTR and the Predicate Device

	Predicate Device	**Subject Device**
Device Name	EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment System	qXR-CTR
510(k) Number	K212624	NA
Regulation	21 CFR 892.2050	21 CFR 892.2050
Regulation Description	radiological computer-assisted software	radiological computer-assisted software

	Predicate Device	Subject Device
Product Code	QIH	QIH
Device type	Quantifying software	Quantifying software
Manufacturer	Ever Fortune.AI Co., Ltd.	Qure.ai Technologies
Intended use / Indications for Use	EFAI Intelligent Cardiothoracic Ratio Assessment System (or iCTR) is a software for use by hospitals and clinics to automatically assess the cardiothoracic ratio (CTR) of a chest X-ray image from the X-ray imager subject. The iCTR is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR of a chest X-ray image in posterior-anterior (PA) chest view using an artificial intelligence algorithm. Intended users of the software are aimed to the physicians or other licensed practitioners in the healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. The system is suitable for adults between 20 - 80 years of age. Its results are not intended to be used on a stand-alone basis for clinical decision making or otherwise preclude clinical assessment of cardiothoracic ratio (CTR) cases.	qXR-CTR is a deep-learning based software for use by hospitals and clinics for automated assessment of the CTR on chest X-ray (CXRs) scans. qXR-CTR is designed to measure the ratio of the maximal transverse diameter of the heart (CD) and the maximal inner transverse diameter (TD) of the thoracic cavity and calculate the CTR value on posterior-anterior view chest view using an artificial intelligence algorithm. The intended users of this device are physicians or licensed practitioners in healthcare institutions, such as clinics, hospitals, residential care facilities, long-term care services, and healthcare facilities. The system is suitable for adults ≥ 22 years of age. The device is used to aid the intended users and results are not intended to be used on a stand-alone basis for clinical decision making or otherwise preclude clinical assessment of CTR cases.
Algorithm for measurement of target structures	AI Algorithm	AI Algorithm
Modality	Chest X-ray in Digital Radiography (DR)	Chest X-ray in Digital Radiography (DR)
Input	Post-anterior (PA) view chest X-ray image	Post-anterior (PA) view chest X-ray image
Input format	DICOM	DICOM
Output Format	Reports, DICOM Secondary Capture series	Pdf report is generated, DICOM Secondary capture is returned to the PACS
Report Structure	Report will be output in the DICOM and JSON file format which is structured with	Report will be output in the DICOM and JSON file format which is structured with following information

	Predicate Device	Subject Device
	following information and function tool: 1) CTR 2) adjustable annotation line (maximal inner border diameter of thoracic cavity and maximal diameter of heart) 3) the trajectory of CTR (including chest X-ray)	and function tool: 1) CTR 2) annotation line (maximal inner border diameter of thoracic cavity and maximal diameter of heart)
Intended User	Physicians or other licensed practitioners in the healthcare institutions	Physicians or other licensed practitioners in the healthcare institutions
Target Population	20-80 years	≥ 22 years
Modality	Chest X-ray in Digital Radiography	Chest X-ray in Digital Radiography
Intended Use Environment	Healthcare institutions (Clinics, hospitals, healthcare facilities, residential care facilities and long-term care services)	Healthcare institutions (Clinics, hospitals, healthcare facilities, residential care facilities and long-term care services)
Software device that operates on off the shelf hardware	Yes	Yes
Software devices uses software algorithms for image	Yes	Yes
Diameter Measurement	Yes	Yes
Storage	Saved in JSON and DICOM file format text for DICOM and DICOM file format	The text report is generated with the CXR scan on a Structured Report (SR) format for PACS-based mode. For the Web-based mode, the user can download a PDF version of the report with the same information
Software Requirement	Ubuntu 18.04 (Web browser: chrome 88.0.4324.182 or above)	Ubuntu 20.04+
Performance metrics of the predicate device and qXR-CTR		
Performance level	RMSE: Cardiac Diameter = 8.81 mm Thoracic Diameter = 14.4 mm Mean Absolute Error: NR	RMSE: Cardiac Diameter = 7.55 mm Thoracic Diameter = 5.43 mm Mean Absolute Error: 5.66 (5.0) mm 4.04 (3.63) mm

7 SOFTWARE TESTING

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.

8 PERFORMANCE TESTING – CLINICAL

The performance of qXR-CTR 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(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-CTR for measuring the cardiac diameter and thoracic diameter.

The study included 435 scans with PA view from various parts of the US. The ground truth was established by 3 ABR thoracic radiologists with a minimum of 10 years of experience. The RMSE of the device in measuring the target structures exceeded the success criteria with RMSE for cardiac diameter being 7.55 (6.95, 8.34) mm and thoracic diameter being 5.43 (4.95, 6.11) mm. The predicate EFAI iCTR Assessment's performance was cardiac diameter RMSE: 8.81 mm and thoracic diameter: 14.4 mm.

Further, the mean absolute error along with standard deviation for both the cardiac and thoracic diameter was measured at 5.66 (5.0) mm and 4.04 (3.63) mm, respectively.

Table 2 Overall Results of Accuracy Testing of qXR-CTR

Measurement	**Root Mean Squared Error (95% CI) in mm**	**Mean Absolute Error (SD) in mm**
Cardiac Diameter	7.55 (6.96, 8.38)	5.66 (5.0)
Thoracic Diameter	5.43 (4.94, 6.09)	4.04 (3.63)
CTR	0.03 (0.02, 0.03)	0.02 (0.02)

9 CONCLUSION

The comparison in Table 1 and the software and performance testing presented above demonstrate that the qXR-CTR device is substantially equivalent to the predicate device. The qXR-CTR is a software only device, similar to the predicate (EFAI iCTR Assessment) and has no new risks related to safety and effectiveness. The qXR-CTR has the same intended users and similar indications, technological characteristics, and principles of operation as the predicate device. Both devices operate in parallel to the standard of care workflow. The performance testing demonstrates that the qXR-CTR performs as intended and is therefore substantially equivalent to the predicate. Software and Clinical testing support that the device performs in accordance with the device requirements.