August 16, 2024

Qure.ai Technologies
Abishamala Kingsly
Senior Regulatory Clinical Affairs Manager
Level 7, Commerz II International Business Park
Oberoi Garden City, Goregaon (E)
MUMBAI, MAHARASHTRA 400 063
INDIA

Re: K240740
Trade/Device Name: qCT LN Quant
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 10, 2024
Received: July 10, 2024

Dear Abishamala Kingsly:

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,

for

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)*

K240740

Device Name

qCT LN Quant

Indications for Use *(Describe)*

qCT LN Quant is a software device used in the tracking, assessment, and quantitative characterization of detected pulmonary nodules. This automatically analyzes user-selected regions within lung CT to provide volumetric, diameter and computer analysis based on morphological characteristics in a single study, or over the time course of several thoracic studies. The system performs the measurements, allowing the preview of lung nodules in 2D and 3D reconstructed views and the respective measurements to be displayed. It is indicated for the evaluation of user detected solid pulmonary nodules.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K240740

510(k) SUMMARY

qCT LN Quant

1 SUBMITTER

Qure.ai Technologies Pvt. Ltd.
Level 7, Commerz II,
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Mumbai - 400 063
Country: INDIA
Phone: +91-9840580965
Primary Contact Person: Abishamala Kingsly, Senior Regulatory Clinical Affairs Manager
Secondary contact person: Bunty Kundnani, Chief Regulatory Affairs Officer

Date Prepared: 29 February 2024

2 SUBJECT DEVICE

Name of Device:	qCT LN Quant
Common or Usual Name:	Medical Image Management and Processing System
Classification Name:	Automated Radiological Image Processing Software
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050
Product Code:	QIH

3 PREDICATE DEVICES

Name of Device:	Ninesmeasure
Manufacturer:	Nines, Inc.
510(k) Number:	K202990
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ

Name of Device:	Lung Nodule Assessment and Comparison Option (LNA)
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Number:	K162484
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050; 21 CFR 892.1750
Product Code	LLZ, JAK

4 INTENDED USE / INDICATIONS FOR USE:

qCT LN Quant is a software device used in the tracking, assessment and quantitative characterization of detected pulmonary nodules. This automatically analyzes user-selected regions within lung CT to provide volumetric, diameter and computer analysis based on morphological characteristics in a single study, or over the time course of several thoracic studies. The system performs the measurements, allowing the preview of lung nodules in 2D and 3D reconstructed views and the respective measurements to be displayed. It is indicated for the evaluation of user detected solid pulmonary nodules.

5 DEVICE DESCRIPTION

Qure.ai's computed tomography (CT) scan software, the qCT LN Quant, is a deep-learning-based device that can process non-contract CT (NCCT) scans and assists in quantitative characterization of solid lung nodules of size ≥ 6mm on Chest CTs.

qCT LN Quant consists of a cloud module that can interacts with DICOM modality or the user's picture archiving and communication system (PACS) to receive de-identified scans and returns the results to the same destination. In addition, solid nodules are segmented by the user semi-automatically using double seed points on the nodule, followed by interactive fine-tuning of the boundaries. The segmented region is quantitatively characterized by qCT LN Quant and presented to users as an additional overlay by highlighting and labelling respectively. User-assisted segmentation generated by qCT LN Quant can be presented in two ways to the users:

a. PACS-based mode: As a new series (secondary capture) which are returned to the originating PACS system with segmentation burnt on the series. This can be done only at PACS which supports GSPS Output.

b. Web-based mode: On Qure's web application where the segmentation is overlaid on top of the original scan.

qCT LN Quant deep learning algorithm has been trained to quantify the target structures on CT scans and is coupled with pre-and post-processing functionality that allows the device to work directly with the radiology workflow. The user is presented with 2D view and 3D reconstructed view of solid nodule images labelling the quantitative characteristics based on the user-segmented structures. The output consists of information on average diameter and volumes of user identified solid nodules. The additional features include long axis diameter (mm), short axis diameter (mm), Effective diameter (mm), and Mean/Minimum/Max HU (HU) and volume change overtime with matched nodules. In addition, qCT LN Quant consists of a Brock Score - Risk Calculator that uses diameter of the nodule and clinician's input. The Lung-RADS^{TM} calculator feature is based on ACR guideline, which can assist the physician in decision making. qCT LN Quant also provides recommendations based on Fleischner's Society guideline. Thus, qCT LN Quant offers functionality to calculate Brock and LungRADS score as part of integrated or cleared devices with capability to display such output.

qCT LN Quant is limited to analysis of imaging data and results generated are meant for information purposes only. The device is not intended for clinical diagnosis of any disease. It does not replace the role of physician or of other testing in the standard of care for lung abnormalities.

KEY FEATURES

Semi-automatic quantification of solid nodule features

- Average Diameter (mm)
- Volume (mm3)

ADDITIONAL FEATURES

- 3D visualization of segmented nodules
- Manual editing of the solid nodule segmentation contour lines with automatic recalculation of quantitative characteristics post-editing
- Automatic software calculation of the following measurements for each segmented nodule:
  - Long Axis- Longest diameter on an axial slice(mm)
  - Short Axis- Longest diameter perpendicular to the long axis on the same slice (mm)
  - Effective diameter (mm) - a formula-based feature calculated from volume of the nodule
  - Measurement of Mean/Minimum/Max HU (HU)
- Volume Doubling Time (VDT) calculated from the measurements between each current scan and the prior scan. This measurement is a formula derived value from existing validated measurements, namely the volume estimate of a region within the current and prior scans. This information is used in a mathematical calculator along with the number of days between the scans to calculate VDT.
- Lung-RADS™ calculation based on information provided by users.
- Brock Score - Risk Calculator tool based on patient and nodule characteristics provided by users. This is used for estimation and alignment of the probability that lung nodules detected on low-dose CT scans are malignant, as reported by McWilliams, Annette, et al. "Probability of cancer in pulmonary nodules detected on first screening CT." New England Journal of Medicine 369.10 (2013): 910-919.
- Reporting based on Fleischner Society guidelines with the aid of user filled patient information.

Additional Information on Brock Score - Risk Calculator:
This is a calculator using Brock University Score as described in McWilliams, et al (2013). This model allows estimating the probability that lung nodules detected on baseline CT scans are malignant. The diameter obtained by the device will be prefilled while the other variables required for the calculator will be user added-. Nodules within each scan will be ordered based on this score.
The model's performance was validated using two large population-based prospective studies: the Pan-Canadian Early Detection of Lung Cancer Study (PanCan) and the chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute.

Further details can be found in McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S. Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine. 2013; 369(10), 910-919.

Additional Information on Lung-RADS™ Classification:
This is a classification system proposed to aid with findings in low-dose CT screening exams for lung cancer. The goal of the classification system is to standardize follow-up and management decisions.

Further details can be found in Martin MD, Kanne JP, Broderick LS, Kazerooni EA, Meyer CA. RadioGraphics Update: Lung-RADS 2022. Radiographics. 2023; 43(11): e230037. doi: 10.1148/rg.230037. PMID: 37856315.

Additional Information on Fleischner's Guidelines:
Fleischner Society guidelines for management of solid or subsolid nodules was created for the purpose of recommendations to reduce the number of unnecessary follow-up examinations while providing greater discretion to the radiologist, clinician, and patient to make management decisions.

MacMahon, Heber, et al. "Guidelines for management of incidental pulmonary nodules detected on CT images: from the Fleischner Society 2017." Radiology. 2017; 284(1): 228-243.

WARNINGS AND PRECAUTIONS

- Conditions of image quality that diminish chest radiographic sensitivity, such as noise or artifacts, may also diminish the effectiveness of the device
- qCT LN Quant is intended to be used by certified medical specialists trained and experienced to review and report chest CT scans.
- qCT LN Quant is not intended to be used in patients with Idiopathic Pulmonary Fibrosis (IPF) and extensive granulomatous disease.
- qCT LN Quant is limited to analysis of imaging data quantification and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.
- The clinician is responsible for reviewing the device findings with the original image for any treatment /transfer initiation.
- The device shall not be used for scans outside of the compatibility as defined in Section 1.8. If used may reduce performance of the quantification device.
- When performing follow-up studies, it is important to use the same parameters as the original CT to get a consistent quantitative characteristics comparison between current and previous studies. If the recommended parameters are not used the accuracy of the results cannot be assured.
- The user has to verify the correctness of the segmentation and labels. If changes are needed, they have to be manually corrected using the correction tools provided by the application.

6 COMPARISON WITH PREDICATE DEVICE

Table 1 Comparison between qCT LN Quant and the Predicate Devices

	Primary Predicate Device	Secondary Predicate Device	Subject Device
Device Name	**NinesMeasure**	**Lung Nodule Assessment and Comparison Option (LNA)**	**qCT LN Quant**
510(k) Number	K202990	K162484	K240740
Device Class	Class II	Class II	Class II
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050	21 CFR 892.2050 21 CFR 892.1750	21 CFR 892.2050
Regulation Description	Radiological Image Processing System	Radiological Image Processing Software	Medical Image Management and Processing System
Product Code	LLZ	LLZ, JAK	QIH
Manufacturer	Nines, Inc	Philips Medical Systems Nederland B.V.	Qure.ai Technologies Pvt. Ltd.
Intended use / Indications for Use	NinesMeasure is a semi-automatic tool indicated for use by trained radiologists to aid in the analysis and review of adult thoracic CT images. NinesMeasure provides quantitative information about pulmonary nodule size on a single study or over the time course of several thoracic studies by providing long and short axis diameter measurements in the axial plane. Based on analysis of DICOM images and provided input from a radiologist, indicating the location of the pulmonary nodule, the device uses artificial intelligence algorithms to	The Philips Medical Systems Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.	qCT LN Quant is a software device used in the tracking, assessment, and quantitative characterization of detected pulmonary nodules. This automatically analyzes user-selected regions within lung CT to provide volumetric, diameter and computer analysis based on morphological characteristics in a single study, or over the time course of several thoracic studies. The system performs the measurements, allowing the preview of lung nodules in 2D and 3D reconstructed views and the respective measurements to be displayed. It is

	Primary Predicate Device	Secondary Predicate Device	Subject Device
Device Name	**NinesMeasure**	**Lung Nodule Assessment and Comparison Option (LNA)**	**qCT LN Quant**
	automatically perform the measurements, and allows the axial measurements to be displayed and reviewed. NinesMeasure is limited for use on solid pulmonary nodules. The device is intended to be used as a measurement tool by a trained radiologist and is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm a diagnosis. The device does not alter the original medical image.		indicated for the evaluation of user detected solid pulmonary nodules.
Intended User	Radiologists	Radiologists and Technologist	Radiologists and Pulmonologists.
Modality	Thoracic CT scan	Thoracic CT scan	Non-Contrast Chest CT scan
Target clinical conditions	Lung Nodule	Lung Nodule	Lung Nodule
Algorithm for pre-specified critical findings detection	Image processing algorithms for nodule measurement	Image processing algorithms for lung nodule measurements	Image processing algorithms for lung nodule measurements
Input format	DICOM	DICOM	DICOM
Performance level – accuracy of classification	Normalized error on long axis diameter – [95% CI] 0.113 [Upper Bound 0.124]. Normalized error on short axis diameter – [95% CI] 0.131 [Upper Bound 0.143]	Not Available	Median Absolute Normalized Average Diameter Error [95% CI]: 11.1 (9.1-11.1) Median Absolute Normalized Volume Error [95% CI]: 20.7 (17.6-22.6)

7 TESTING

Software:

Software verification and validation testing was executed, and documentation was provided as recommended by FDA's Guidance for the Content of Premarket Submission for Device Software Functions (June 2023). During all verification and validation tests carried out for the qCT LN Quant software, which included evaluating both the algorithmic functionality and the overall performance of the software and its components, qCT LN Quant functioned as designed and successfully met the anticipated performance criteria.

Verification, validation, and testing activities were conducted to establish the performance, functionality, and reliability characteristics of the device. Unit Test, Integration Test, Regression Test and User Acceptance test were carried out to account towards the device's performance non-clinically. Functional testing is done to assess functional requirements of the product. The device passed all the tests based on determined acceptance criteria. Standards Regulatory references Used are ISO 13485: 2016 and IEC 62304:2006+A1:2015.

Clinical Performance Testing:

Annotation Process: The dataset used in the study included 216 solid nodules identified from a total of 118 chest CT scans from 104 subjects. Ground Truth was established by three expert radiologists. The truthers independently read the scans and mark out the boundaries of the nodule in all slices -

Testing Summary: Performance of the qCT LN Quant device in quantitative characterization of solid nodules was assessed using the standalone study. The device showed good performance and met the predefined success criteria when evaluated against the ground truth (reference standard). The study results also indicated that the outputs of the device are accurate and uniform across a wide range of potential sources of measurement error.

Table 2 Standalone Performance Testing Results for qCT LN Quant

Measurements	Median Absolute Normalized Error %	95% Confidence Interval
Short Axis Diameter	14.3	13.95 - 16.67
Long Axis Diameter	11.1	9.52 - 12.50
Volume	20.7	17.29 - 22.41

8 CONCLUSION

The comparison in Table 1 as well as the software & performance testing presented above demonstrate that the qCT LN-Quant device is substantially equivalent to the predicate devices. Both the subject and predicate devices are medical image analyzers intended to read chest CT scans to quantitatively characterize user identified lung nodules. The algorithms function similarly and with the same purpose of quantitative characterization of lung nodules. The new device does not introduce

fundamentally new scientific technology, and the clinical tests demonstrate that the device is safe and effective as predicate.

The qCT LN Quant is a software only device with similar indications, technological characteristics, and principles of operation as the predicate devices. The comparison of intended purpose, technological characteristics and performance demonstrates that the qCT LN-Quant device performs as intended and can be considered as substantially equivalent to the predicate devices, Lung Nodule Assessment and Comparison Option (LNA) (K162484) and NinesMeasure (K202990).