September 14, 2026

Qure.ai Technologies Pvt., Ltd.
℅ Smina T P
Senior Technical Lead - Regulatory & Clinical Affairs
6TH FLOOR, WING E, TIMES SQ., ANDHERI- KURLA RD., MAROL
ANDHERI (EAST)
MUMBAI, MAHARASHTRA 400059
INDIA

Re: K261517
Trade/Device Name: qCT Lung (v1.0)
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: August 17, 2026
Received: August 17, 2026

Dear Smina T P:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
DHT8B: Division of Radiologic Imaging
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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.

510(k) Number *(if known)*
K261517

Device Name
qCT Lung (v1.0)

Indications for Use *(Describe)*
The qCT Lung is a diagnostic image analysis tool intended to be used as a concurrent reader for the analysis of CT scans from lung cancer screening population. qCT Lung assists radiologists and pulmonologists in the detection of pulmonary nodules of size 4-30 mm, provides characterization, and quantification of the region of interest (ROI). Characterization of nodules involves features of texture (solid, part-solid, and ground glass), spiculation status, and calcification status. Quantification includes information on the volume and diameter of the region of interest.

qCT Lung provides adjunctive information and is not intended to be used as a replacement for a complete interpreting physician's review or clinical judgment. qCT Lung is also not intended to be used without the original CT series.

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

qCT LUNG v1.0

K261517

1 SUBMITTER

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Date Prepared: 06 May 2026

2 SUBJECT DEVICE

Name of Device:	qCT Lung (v1.0)
Common or Usual Name:	Radiological Computer-Assisted Detection And Diagnosis Software
Classification Name:	Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2090
Product Code:	QDQ

3 PREDICATE DEVICE

Name of Device:	Lunit INSIGHT DBT v1.1
Manufacturer:	Lunit Inc.
510(k) Number:	K242652
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2090
Product Code	QDQ

4 REFERENCE DEVICES

Name of Device:	ClearRead CT
Manufacturer:	Riverain Technologies, LLC
510(k) Number:	K161201
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2050
Product Code	OEB, 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

5 INDICATIONS FOR USE

The qCT Lung is a diagnostic image analysis tool intended to be used as a concurrent reader for the analysis of CT scans from lung cancer screening population. qCT Lung assists radiologists and pulmonologists in the detection of pulmonary nodules of size 4-30 mm, provides characterization, and quantification of the region of interest (ROI). Characterization of nodules involves features of texture (solid, part-solid, and ground glass), spiculation status, and calcification status. Quantification includes information on the volume and diameter of the region of interest.

qCT Lung provides adjunctive information and is not intended to be used as a replacement for a complete interpreting physician's review or clinical judgment. qCT Lung is also not intended to be used without the original CT series.

6 INTENDED USER

The intended users of the qCT Lung are radiologists and pulmonologists who are trained and experienced in the independent review and interpretation of CT scans.

7 INTENDED PATIENT POPULATION

qCT Lung is intended to be used for reviewing CT examinations from adult screening population.

8 DEVICE DESCRIPTION

Qure.ai's computed tomography (CT) scan software, the qCT Lung, is an artificial intelligence-based device that can process non-contrast CT scans and assist the radiologists and pulmonologists in detecting the pulmonary nodules, characterizing, and quantifying the region of intertest (ROI). Characterization of nodules involves features of texture (solid, part-solid and ground glass), spiculation status (present/absent), and calcification status (present/absent). Quantification of the region of interest will include volume and diameter information.

qCT Lung's algorithm has been trained to process the incoming DICOM images allowing detection of nodules along with characterization and quantification of region of interest. The software works with DICOM CT images and can be deployed on a secure cloud server or on-premises server. qCT Lung consists of a cloud module that can interact with DICOM modality or the user's picture archiving and communication system (PACS) to receive de-identified scans and return the results to the same destination. The core processing module consists of a pre-trained convolutional neural network (CNN). This core processing module is coupled with a pre-processing module that prepares input DICOM files for processing by the CNN and a post-processing module that converts the output of the CNN into visual output in the form of an overlay showing the results.

Pulmonary nodules are segmented by the device initially, after which the user can verify the correctness of the segmentation and labels. If changes are required, they can manually correct the

segmentation and labels using editing tools provided by the application. The segmented region is characterized and quantitatively measured by qCT Lung. The detection, characterization, and quantification results are presented to users as an additional overlay by highlighting and labelling, respectively. Results generated by qCT Lung 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 or as GSPS overlay if supported by PACS.

b. Web-based mode: On Qure's web application where secondary capture and its derived visualisations are shown along with output labels for review.

qCT Lung contains an artificial intelligence-based deep learning algorithm built on a convolutional neural network (CNN) architecture, pre-trained from a CT foundation model and fine-tuned for lung nodule detection, characterization, and quantification on CT images. The algorithm has been trained to detect the pulmonary nodules, characterize and quantify the region of interest on CT scans and is coupled with pre-and post-processing functionality that allows the device to work directly with the radiology workflow. The characterization feature output consists of information on nodule texture, calcification status and spiculation status. The quantitative feature output consists of information on average diameter and volumes of the region of interest. The additional features include long axis diameter (mm) and short axis diameter (mm).

qCT Lung 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:

- Detection and localization of pulmonary nodules
- Characterization of detected pulmonary nodules
  - Calcification status
  - Spiculation status
  - Texture (solid, ground glass, part-solid)
- Quantification of the region of interest
  - Average Diameter (mm)
  - Volume (mm^3)

Additional Features:

Computation of the following measurements for each segmented region of interest:

- Long Axis - Longest diameter on an axial slice (mm)
- Short axis - Longest diameter perpendicular to the long axis on the same slice (mm)

9 COMPARISON WITH PREDICATE DEVICE

Table 1 Comparison between qCT Lung (v1.0) and the Predicate Devices

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
Device Name	**qCT Lung (v1.0)**	**Lunit INSIGHT DBT v1.1**	**ClearRead CT**	**Lung Nodule Assessment and Comparison Option (LNA)**
510(k) Number	K261517	K242652	K161201	K162484
Manufacturer	Qure.ai Technologies Pvt. Ltd.	Lunit Inc.	Riverain Technologies, LLC	Philips Medical Systems Nederland B.V.
Device Class	Class II	Class II	Class II	Class II
Device Classification Name	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer	Radiological Computer Assisted Detection/Diagnosis Software For Suspicious Lesions For Cancer	System, Image processing, Radiological	System, Image processing, Radiological
Regulation Number	21 CFR 892.2090	21 CFR 892.2090	21 CFR 892.2050	21 CFR 892.2050 21 CFR 892.1750
Regulation Description	Radiological Computer Assisted Detection And Diagnosis Software	Radiological Computer Assisted Detection And Diagnosis Software	Medical image management and processing system	Medical image management and processing system
Product Code	QDQ	QDQ	OEB, LLZ	LLZ, JAK
Intended use / Indications for Use	The qCT Lung is a diagnostic image analysis tool intended to be used as a concurrent reader for the analysis of CT scans from lung cancer screening population. qCT Lung assists radiologists and pulmonologists in the detection of pulmonary nodules of size 4-30 mm, provides characterization, and quantification of the region of interest (ROI). Characterization	Lunit INSIGHT DBT is a computer-assisted detection and diagnosis (CADe/x) software intended to be used concurrently by interpreting physicians to aid in the detection and characterization of suspected lesions for breast cancer in digital breast tomosynthesis (DBT) exams from compatible DBT	ClearRead CT™ is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population. The ClearRead CT requires	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

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
Device Name	**qCT Lung (v1.0)**	**Lunit INSIGHT DBT v1.1**	**ClearRead CT**	**Lung Nodule Assessment and Comparison Option (LNA)**
	of nodules involves features of texture (solid, part-solid, and ground glass), spiculation status, and calcification status. Quantification includes information on the volume and diameter of the region of interest. qCT Lung provides adjunctive information and is not intended to be used as a replacement for a complete interpreting physician's review or clinical judgment. qCT Lung is also not intended to be used without the original CT series.	systems. Through the analysis, the regions of soft tissue lesions and calcifications are marked with an abnormality score indicating the likelihood of the presence of malignancy for each lesion. Lunit INSIGHT DBT uses screening mammograms of the female population. Lunit INSIGHT DBT is not intended as a replacement for a complete interpreting physician's review or their clinical judgment that takes into account other relevant information from the image or patient history.	both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.	over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.
Intended User	Radiologists and Pulmonologists	Physicians interpreting screening mammograms	Trained Medical Professionals	Radiologists and Technologist
Target Patient Population	Adult screening population	Women undergoing mammography	Asymptomatic population	Diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening
Target clinical conditions	Lung Nodule	Suspected lesions for Breast cancer	Lung Nodule	Lung Nodule
Modality	Non-Contrast CT scan	Digital Breast Tomosynthesis (DBT) images	Thoracic CT scan	Thoracic CT scan

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
Device Name	**qCT Lung (v1.0)**	**Lunit INSIGHT DBT v1.1**	**ClearRead CT**	**Lung Nodule Assessment and Comparison Option (LNA)**
Fundamental Technological Basis	Artificial intelligence-based deep learning algorithm built on a Convolutional Neural Network (CNN) architecture pre-trained using a CT foundation model and fine-tuned	Artificial intelligence / machine learning-based software algorithm	Artificial intelligence / machine learning-based software algorithm	Artificial Intelligence based software algorithm
Input format	CT images provided in a DICOM format	Digital Breast Tomosynthesis (DBT) images	CT images provided in a DICOM format	CT images provided in a DICOM format
Device Output Format	DICOM format output containing the region of interest marked with contour lines and labelled overlays indicating the texture, spiculation status, calcification status, volume, average diameter, long axis, and short axis, suitable for viewing in the PACS or radiology viewer.	Output that includes the lesion type, location, lesion-level/case-level score, and outline of the regions suspected of breast cancer	DICOM format output containing ROIs which are displayed as overlays with computed characteristics – avg density (HU), max diameter (mm), min diameter (mm) and volume (mm^3)	Output containing patient related information, dictation Table with Nodule result table and additional findings LungRADS and Risk Calculator
Device Features	Detection Characterization: • Texture (solid, part-solid, ground glass) • Spiculation Status • Calcification Status Quantification: • Nodule Volume (mm3) • Average Diameter (mm) • Long Axis Diameter (mm)	Detection • Characterization: • Lesion type • Location • Calcifications Lesion-level/case-level score	Detection • Volume • Maximum diameter • Minimum diameter • Density	Quantification: • Short axis (mm) • Long Axis (mm) • Average diameter (mm) • Max 3D diameter (mm) • Effective diameter (mm) • Volume (mm3) • Mean densities (HU) Characterization:

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
Device Name	**qCT Lung (v1.0)**	**Lunit INSIGHT DBT v1.1**	**ClearRead CT**	**Lung Nodule Assessment and Comparison Option (LNA)**
	• Short Axis Diameter (mm)			• Nodule type (solid, part-solid, ground-glass, calcified) • Lobe Location • Nodule shape (Circular/Oval/Triangular) • Nodule Spiculation Comparison and matching features: • Doubling time in days • Percent (%) and absolute change of all numerical parameters (growth in nodule long axis, short axis, average diameter, max 3D diameter, effective diameter, volume, mean HU).
Lesion Detection	Yes	Yes	Yes	No - user identified nodules
Characterization	Yes	Yes	No	Yes

10 TESTING

10.1. Software Testing

Software verification and validation testing were 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 Lung software, which included evaluating both the algorithmic functionality and the overall performance of the software and its components, qCT Lung 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 the 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.

10.2. Standalone Study Performance Testing

Standalone study was conducted to estimate the performance of qCT Lung in detecting the pulmonary nodules, characterizing, and quantifying the region of intertest in low-dose CT (LDCT) scans. A total of 670 scans (462 with at least one nodule and 208 without nodules) were used to evaluate the performance of qCT Lung. The reference standard was established by three American Board of Radiology (ABR)–certified thoracic radiologists each with more than 10 years of experience.

The primary endpoints demonstrating the success of the study, along with the results of the standalone study, are summarized in Table 2.

Table 2: Standalone Performance Testing of qCT Lung

Endpoints	Results (95% CI)
Scan-level AUROC	0.912 (0.892-0.933)
AUROC (calcification)	0.959 (0.925-0.994)
AUROC (spiculation)	0.851 (0.816-0.885)
AUROC (texture)	Macro AUC: 0.934 (0.915-0.950) AUC Solid: 0.917 (0.896-0.939) AUC Part-solid: 0.935 (0.911-0.959) AUC GGN: 0.951 (0.926-0.975)
Mean bias: Bland-Altman analysis for average diameter	−0.36 mm (95% CI: −0.47 to −0.24)
Limits of Agreement (LOA): Bland-Altman analysis for average diameter	Lower LoA (95% CI): -3.48 mm (-3.83 to -3.15) Upper LoA (95% CI): 2.77 mm (2.44 to 3.15)
MANE for average diameter	0.093 (0.085-0.097)
Mean bias - Bland-Altman analysis for volume	+2.4% (95% CI: +0.2 to +4.6)
Limits of Agreement (LOA): Bland-Altman analysis for volume	Lower LoA % (95% CI): −41.7 (−43.5 to −39.7) Upper LoA % (95% CI): +79.8 (+73.1 to +86.6)
MANE for volume	0.18 (0.169-0.201)

Overall, the results indicate that qCT Lung consistently met the predefined success criteria across detection, quantification, and characterization endpoints when evaluated against the ground truth (reference standard). The consistent and strong performance across diverse metrics and subtype-

specific analyses supports its intended use as a decision-support tool to assist radiologists and pulmonologists in pulmonary nodule evaluation, potentially enhancing diagnostic consistency and efficiency. 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.

10.3. Clinical Performance Testing using MRMC Study

A multi-reader multi-case (MRMC) study was conducted to evaluate the performance of readers with (aided) and without the aid (unaided) of qCT Lung. A total of 300 cases, which consisted of 200 diseased scans and 100 non-diseased scans, were used to evaluate the performance of qCT Lung. The MRMC study was performed with 16 readers, including radiologists and pulmonologists spanning varying levels of clinical experience.

The results of the MRMC study are summarized in Table 3.

Table 3: Overall Performance Metrics for the MRMC Study

Endpoints	Unaided	Aided	Difference
Detection: wAFROC (95% CI)	0.655 (0.596, 0.714)	0.763 (0.707, 0.819)	0.108 (0.074, 0.142)
Calcification: Accuracy -ORH Method (95% CI)	51.85% (44.37, 59.33)	66.11% (57.70, 74.52)	14.26% (10.92, 17.60)
Texture: Accuracy - ORH Method (95% CI)	46.17% (39.39, 52.95)	60.79% (52.78, 68.80)	14.62% (11.28, 17.96)
Spiculation: Accuracy - ORH Method (95% CI)	45.64% (38.43, 52.85)	60.35% (52.05, 68.65)	14.71% (11.24, 18.19)

The MRMC study results demonstrate that qCT Lung assistance significantly improves the performance of the readers across all primary and secondary endpoints, with consistent benefits observed across reader specialties and experience levels. The device not only improves the detection of pulmonary nodules but also enhances the accuracy of their characterization, which is critical for decision-making and patient management in clinical workflows.

11 PREDETERMINED CHANGE CONTROL PLAN

The qCT Lung submission contains a Predetermined Change Control Plan (PCCP). Modifications to the algorithm of qCT Lung will be made in accordance with the guidelines outlined in the “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions”. The PCCP describes the modifications that can occur in a controlled manner, ensuring continued safety, effectiveness, and performance of the device.

The algorithm modification will not include any adaptive algorithms that can continuously learned from the environment. According to the modification outlined in the PCCP, any change will only occur after training, testing, and validating the algorithm after which the change will be locked. When the modification is locked this will be communicated to all users through updated labelling via the Instructions for use. Verification and Validation activities will be conducted in accordance with the PCCP to compare the performance of the modified qCT Lung algorithms to the original model to ensure the safety and effectiveness. The modification details are summarized as follows:

Table 4 Details of Modification involved in PCCP

Modification	Rationale	Testing Methods	Impact Assessment (including Benefits, Risks & Mitigations)
M1 – Data-Driven Retraining (CNN architecture unchanged)	Improve the algorithm performance	Retraining with newly acquired, high-quality adult CT datasets including scans from lung cancer screening population, followed by locked test-set evaluation and comparison to baseline model using predefined acceptance criteria	**Benefits:** Improved detection and characterization of lung nodules. **Risks:** Potential overfitting and unintended bias if new data are imbalanced; risk of minor performance variability. **Risk Mitigation:** The modified model will be tested against an independent validation dataset.

12 CONCLUSION

The comparisons provided in Table 1 as well as the software and performance testing demonstrate that overall intended purpose, indications for use and methodological aspects of subject and predicate devices are the same. The subject and predicate devices have been classified under 21 CFR 892.2090 as Radiological Computer Assisted Detection and Diagnosis Software (Product Code: QDQ) and the classification aligns with their intended use and regulatory status. The comparison of technological characteristics demonstrates that qCT Lung is substantially equivalent to the predicate device and comparable to the reference devices, with similar modes of operation. The performance evaluation tests, including both standalone and MRMC studies, also assured that qCT Lung performs as indented and is as effective as the previously cleared predicate and reference devices.

Although the subject and predicate devices differ in anatomical focus (lung vs. breast), modality (CT vs. DBT), they share the same intended purpose to assist physicians in identifying and characterizing the suspicious lesions as a concurrent diagnostic support tool. When comparing with the reference devices, qCT Lung combines the functionalities of the reference devices ClearRead CT and LNA into a single integrated device. The technology, software architectures, algorithm and the operating procedure for the reference devices are similar to the subject device. All the four devices are intended as adjuncts to image interpretation, not as replacements for physician judgment. The minor technological differences between these devices are considered low risk, and they do not raise any questions or concerns about safety and effectiveness. The subject device does not introduce fundamentally new scientific technology, and the clinical tests demonstrate that the device is safe and effective.