October 2, 2025

Thirona BV
% Eva Van Rikxoort
CEO
Toernooiveld 300
NIJMEGEN, 6525 EC
NETHERLANDS

Re: K250766
Trade/Device Name: LungQ 4
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 10, 2025
Received: September 2, 2025

Dear Eva Van Rikxoort:

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.

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,

for

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)*
K250766

Device Name
LungQ 4

Indications for Use *(Describe)*
The Thirona LungQ software provides reproducible CT values for pulmonary tissue and specified endobronchial implants which is essential for providing quantitative support for diagnosis, treatment planning and follow up examination. The LungQ software can be used to support physician in the diagnosis and documentation of pulmonary tissues images (e.g., abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, estimated chronic perfusion defect analysis, fissure evaluation and reporting tools are provided.

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

1. SUBMITTER

Submitted by:

Thirona BV
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6525 EC Nijmegen
the Netherlands

Contact Person:

Eva van Rikxoort

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Date Prepared: 1st October 2025

DEVICE

Trade Name	LungQ 4
Common Use/Usual Name	Computer Tomography X-ray system
Product Code	JAK
Classification	Class II, 21 CFR 892.1750
Device Panel	Radiology

PREDICATE DEVICE

Predicate Device	LungQ v3.0.0
Predicate Classification	Class II, 21 CFR 892.1750

2. REFERENCE DEVICE

Reference Device	Thoracic VCAR with GSI Pulmonary Perfusion
Reference Classification	Class II, 21CFR 892.2050

DEVICE DESCRIPTION

The LungQ software is designed to aid in the interpretation of Computed Tomography (CT) scans of the thorax that may contain pulmonary abnormalities. LungQ is a docker image with a stand-alone command-line software which must be run from a command-line interpreter and does not have a graphical user interface.

INDICATION FOR USE

The Thirona LungQ software provides reproducible CT values for pulmonary tissue and specified endobronchial implants which is essential for providing quantitative support for diagnosis, treatment planning and follow up examination. The LungQ software can be used to support physicians in the diagnosis and documentation of pulmonary tissues images (e.g., abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, estimated chronic perfusion defect analysis, fissure evaluation and reporting tools are provided.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 1 below compares the Thirona LungQ 4 software to the predicate device.

Table 1: Substantial Equivalence Comparison between Subject and Predicate

Item	LungQ 4 Thirona (Subject device)	LungQ v3.0.0 Thirona (Predicate Device)
510(k) Number	K250766	K232412
Product Code	JAK	Same
Regulation Number	21 CFR 892.1750	Same
Device Classification	Class II	Same
Common Name	Computed tomography x-ray system	Same
Indication for use	The Thirona LungQ software provides reproducible CT values for pulmonary tissue and specified endobronchial implants which is essential for providing quantitative support for diagnosis, treatment planning and follow up examination. The LungQ software can be used to support physician in the diagnosis and documentation of pulmonary tissues images (e.g., abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, estimated chronic perfusion defect analysis, fissure evaluation and reporting tools are provided.	Equivalent
Modality	CT	Same
Data Loading	DICOM	Same
Application	Command-line interface	Same
Segmentation	Provides 3D segmentation	Same
	Provides Segmentation of the: • Left Lung • Right Lung • Left Upper Lobe • Left Lower Lobe	Same

	• Right Upper Lobe • Right Middle Lobe • Right Lower Lobe • Pulmonary (sub)segments	
	Provides Segmentation of the: Airways	Same
	Provides segmentation of specified endobronchial implants	Equivalent
Lung Volume Analysis Support	Ability to measure volume for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe • Left Lower Lobe • Right Upper Lobe • Right Middle Lob • Right Lower Lobe • Pulmonary (sub)segments	Same
Volume Density Analysis	Ability to measure volume at multiple density ranges for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe • Left Lower Lobe • Right Upper Lobe • Right Middle Lob • Right Lower Lobe • Pulmonary (sub)segments	Same

	Ability to measure the 15th percentile density analysis	Same
Fissure Analysis	Ability to perform fissure evaluations	Same
Endobronchial implant analysis	Ability to report the number of specified endobronchial implants in the lungs.	Equivalent
Estimated chronic perfusion defect analysis	Ability to report estimated chronic perfusion defect quantification for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe • Left Lower Lobe • Right Upper Lobe • Right Middle Lob • Right Lower Lobe • Pulmonary (sub)segments	Equivalent
Analyzed Data Output	Provides a report	Same

PERFORMANCE DATA

The performance testing for LungQ 4 consists of norm-compliance testing, design verification and validation testing. For norm-compliance and design verification, the testing was performed per subject device, while the validation, such as non-clinical validation and usability validation, were performed at system level representing a logical clinical workflow following the intended use.

Performance testing data of the proposed devices demonstrate that the subject device is substantially equivalent to the predicate device, and that the design output meets the design input requirements.

Performance Testing

Software Verification testing was conducted to ensure that the LungQ 4 software met its requirements. The verification testing included white box testing to verify implementation and system integration testing. The LungQ 4 software successfully passed the verification testing.

Software Validation was conducted to ensure the software met the user needs (i.e. input requirements). This validation was based on user scenarios. The LungQ 4 software successfully passed the software validation.

Human factors (HF) engineering process was followed in accordance with the usability standard and FDA guidance. The restricted interface of LungQ 4 with the third party end-user-interface is well controlled by the use of standard input and output formats. The usability is determined by the input requirements, which have been identified during risk management. The human factors validation test (summative usability evaluation) of LungQ 4 was performed.

Substantial equivalence Study

A head-to-head performance testing was conducted between the subject and the predicate device. The aim of this study was to assess and compare the measurement of lung structure parameters, such as (sub)segment volume and density analysis, density scores (LAA-950HU and LAA-910HU) and airway segmentation analysis between LungQ 4 (subject device) and LungQ v3.0.0 (predicate device, K232412). The results showed that for volume, density scores and airway segmentation, the acceptance criteria were met.

In addition, a study has been performed to provide performance testing of the endobronchial implant analysis feature. The study dataset included multi-center CT scans of patients that underwent endobronchial valve (EBV) treatment and CT scans from negative controls (i.e. patients eligible for EBV treatment but without EBV). Reference valve segmentations have been annotated on the dataset by clinical truthers and output metrics are directly compared to the reference Detection performance was evaluated by calculating the sensitivity and precision of the valve analysis component. A valve detection sensitivity ≥ 95% and a valve detection precision of ≥ 90% was achieved and therefore the performance of the valve analysis component met the acceptance criteria.

The added CT derived chronic perfusion defect analysis feature estimates chronic perfusion defects from CT images, similarly to GSI in the Reference Device. The feature was evaluated on a clinical dataset of patients who underwent HRCT and planar perfusion scintigraphy or HRCT and SPECT-CT. Two separate analyses were performed to compare reference perfusion scores (either extracted from planar perfusion scintigraphy or SPECT-CT) to the LungQ 4 CT derived chronic perfusion defect scores. Agreement between LungQ 4 and both planar perfusion scintigraphy and SPECT-CT was assessed through intra-class correlation coefficients (ICC) and Bland-Altman analysis. An ICC > 0.75, bias < 5% and limits of agreements between -10% and 10% were required for estimated chronic perfusion defect measurements and reference perfusion scores for the left lung, right lung and each of the individual lobes. In addition to the direct comparison of perfusion values, experienced pulmonologists reviewed whether the use of LungQ 4 CT derived chronic perfusion defect analysis would provide similar quantitative support for treatment planning as SPECT-CT. The results confirmed that the provided quantitative support was the same for LungQ 4 and SPECT-CT. All acceptance criteria for direct comparison and treatment planning support have been met. We conclude that LungQ 4 is similar to the chosen reference device for chronic perfusion defect measurement method in terms of technological characteristics and does not raise new questions on the safety and effectiveness.

Conclusion on performance testing

All compliance, verification and validation tests have been used to support substantial equivalence of the subject device and to demonstrate that the LungQ 4 device:

- comply with the aforementioned international and FDA recognized consensus standards and FDA guidance documents; and
- meet the acceptance criteria and are adequate for their intended use.

Based on the information provided above, the LungQ 4 device is considered substantially equivalent to the predicate device in terms of safety and effectiveness.

No clinical testing was required as substantial equivalence was demonstrated by the attributes of intended use, technological characteristics, and non-clinical testing.

CONCLUSIONS

The proposed device, LungQ 4, is substantially equivalent to the above-mentioned predicate device, in terms of intended use, technological characteristics and, safety and effectiveness.

Substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that the proposed device comply with the user needs specifications and product requirements, as well as the requirements specified in the international and FDA-recognized consensus standards, and are as safe and effective as the predicate device, and do not raise any new safety and/or effectiveness concerns.