January 8, 2024

Thirona BV
℅ Eva Rikxoort
Official Correspondent
Toernooiveld 300
Toernooiveld 300, 6525 EC
NETHERLANDS

Re: K232412
Trade/Device Name: LungQ v3.0.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: August 10, 2023
Received: December 6, 2023

Dear Eva 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.

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.
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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)*
K232412

Device Name
LungQ V3.0.0

Indications for Use *(Describe)*
The Thirona LungQ software provides reproducible CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis 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, 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.

Section 5 510(k) Summary

5.1 SUBMITTER

Submitted by:

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Contact Person:

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Date Prepared: 8th August 2023

5.2 DEVICE

Trade Name	LungQ v3.0.0
Common Use/Usual Name	Computer Tomography X-ray system
Product Code	JAK
Classification	Class II, 21 CFR 892.1750
Device Panel	Radiology

5.3 PREDICATE DEVICE

Predicate Device	LungQ v1.1.0
Predicate Classification	Class II, 21 CFR 892.1750

5.4 REFERENCE DEVICE

Predicate Device	VIDA|Vision
Predicate Classification	Class II, 21 CFR 892.1750

5.5 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 stand-alone command-line software which must be run from a command-line interpreter and does not have a graphical user interface.

5.6 INDICATION FOR USE

The Thirona LungQ software provides reproducible CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis 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, fissure evaluation, and reporting tools are provided.

5.7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 5-1 below compares the Thirona LungQ software to the predicate device.

Table 5-1: Substantial Equivalence Comparison between Subject, Predicate and Reference Device

Item	LungQ v3.0.0 Thirona (Subject Device)	LungQ v1.1.0 Thirona (Predicate Device)	VIDA|vision VIDA Diagnostics, Inc (Reference Device)
510(k) Number	NA	K173821	K200990
Product Code	JAK	Same	Same
Regulation Number	21 CFR 892.1750	Same	Same
Device Classification	Class II	Same	Same
Common Name	Software Accessory to a Computed tomography x-ray system	Same	Same
Intended Use	The Thirona LungQ software provides reproducible CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis 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	Same	Equivalent

	segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, fissure evaluation, and reporting tools are provided.		
Modality	CT	Same	Same
Data Loading	DICOM	Same	Same
Application	Command-line interface	Same	Equivalent
OS	Linux	Equivalent	Equivalent
Segmentation	Provides 3D segmentation	Same	Same
	Provides Segmentation of the: • Left Lung • Right Lung • Left Upper Lobe • Left Lower Lobe • Right Upper Lobe • Right Middle Lobe • Right Lower Lobe • Pulmonary (sub)segments	Equivalent	Equivalent
	Provides Airways Segmentation	Same	Same
	User cannot manually edit segmentation	Same	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	Equivalent	Equivalent
Volume Density Analysis	Ability to measure volume at multiple density ranges for: • Both Lungs	Equivalent	Equivalent

	• Left Lung • Right Lung • Left Upper Lobe • Left Lower Lobe • Right Upper Lobe • Right Middle Lob • Right Lower Lobe • Pulmonary (sub)segments		
	Ability to measure the 15th percentile density analysis	Same	Same
Fissure Analysis	Ability to perform fissure evaluations	Same	Same
Analyzed Data Output	Provides a report	Same	Same

5.8 PERFORMANCE DATA

The performance testing for LungQ 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.

Compliance Testing

Norm-compliance performance tests were performed on the proposed LungQ software according to the following FDA recognized consensus standards and FDA guidance documents (see **Table 5-2** and **Table 5-3**), and were all passed.

Table 5-2: Standards and Guidance documents

Identification Number	Edition / Year	Title	Rec Number
AAMI TIR57	2016	Principles for medical device security—Risk management	13-83
ANSI AAMI IEC TIR 80002-1	2009	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	13-34
ANSI NEMA HN 1	2019	Manufacturer Disclosure Statement for Medical Device Security	13-123

IEC 62304	1.1/2015	Medical device software - Software life-cycle processes	13-79
IEC 62366-1	1.1/2020	Medical devices - Application of usability engineering to medical devices	5-129
IEC 82304-1	1.0/2016	Health software - Part 1: General requirements for product safety	13-97
ISO 14971	3/2019	Medical devices - Application of risk management to medical devices	5-125
ISO 15223-1	4/2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	5-117
ISO 20417	1/2021	Medical devices — Information to be supplied by the manufacturer	5-135
ISO/IEC 21778	1/2017	Information technology — The JSON data interchange syntax	-
ISO/IEC 27001	2/2013	Information technology — Security techniques — Information security management systems — Requirements	-
NEMA PS 3.1 - 3.20	2022d	Digital Imaging and Communications in Medicine (DICOM) Set	12-349

Table 5-3: Guidance documents

Identification Number	Year	Title
FDA-1997-D-0029	2002	General Principles of Software Validation
FDA-2011-D-0469	2016	Applying Human Factors and Usability Engineering to Medical Devices
FDA-2011-D-0652	2014	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
FDA-2014-D-0456	2018	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
FDA-2015-D-4852	2017	Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices
FDA-2016-D-1853	2021	Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)
FDA-2018-D-1329	2019	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions
FDA-2019-D-3598	2019	Off-The-Shelf Software Use in Medical Devices
FDA-2021-D-0775	2023	Content of Premarket Submissions for Device Software Functions
FDA 2021-D-1158	2022	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
FDA-2023-D-1030	2023	Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act

Performance Testing

Software Verification testing was conducted to ensure that the Lung Q software met its requirements. The verification testing included white box testing to verify implementation and system integration testing. The LungQ 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 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 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 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 lung and lobar volumes, density scores (LAA-950HU and LAA-910HU), 15th percentile lung density (PD15), and fissure completeness between LungQ v3.0.0 (subject device) and LungQ v1.1.0 (primary predicate, K1738210). Firstly, both devices analyzed the lung and lobar volumes, density scores, PD15 and fissure completeness. Subsequently, Bland-Altman plots were used for the pairwise comparison of lung and lobar volumes, density scores, PD15 measurements between the two devices. Moreover, for comparison of the fissure completeness measurements between both devices, receiver operating characteristic (ROC) analysis was performed and the area under de ROC curve (Az value) was calculated. The tolerable variability for absolute and relative threshold values was defined as:

- Lung and lobar volume: Difference ≤ 10%
- Lung and lobar density measurements:
    - LAA-950HU: Agreements limits -1% to 1%
    - LAA-910HU: Agreement limits -10% and 10%
    - 15^{th} Percentile: Agreement limits -10 HU to 10 HU
- Fissure completeness classification: Az value ≥ 0.95

The (sub)segmental volumes and density scores were not compared with the primary predicate but with segmentation which were corrected by human experts. The pairwise comparison between LungQ v3.0.0 and the experts was performed using Blant-Altman analysis of (sub)segmental volumes and density scores. The tolerable variability for absolute and relative values are 150mL and 5%, respectively.

The results showed that for the lung and lobar volumes, density scores (LAA-950HU and LAA-910HU), and 15th percentile lung density (PD15), the difference between LungQ v3.0.0 (subject device) and

the primary predicate were less than the threshold value. The area under the AUC curve (Az value) for the comparison of fissure completeness measurements between LungQ v3.0.0 (subject device) and the primary predicate was found to be 0.97, above the minimal threshold value. The mean difference (SD) between LungQ v3.0.0 and the reference of the human experts for the (sub)segmental volumes and density scores were less than the threshold value.

The scans were taken with a wide variety of scanners. The CT scanner brands and models used to obtain scans in the datasets used for the equivalence study testing are shown in **Table 5-4**.

Table 5-4: Imaging parameters equivalence study.

Imaging parameters Equivalence study	
Scanner manufacture	GE MEDICAL SYSTEMS; SIEMENS; Philips
Scanner types	LightSpeed16; LightSpeed VCT; Sensation 64; Definition; Sensation 16; Definition AS+; SOMATOM Definition Flash; Brilliance 64; LightSpeed Pro 16; Discovery CT750 HD; SOMATOM Definition; LightSpeed Ultra SOMATOM Definition AS; LightSpeed16

The results showed that outputs from Thirona LungQ v3.0.0 are equivalent to the predicate device, LungQ v1.1.0.

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 v3.0.0 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 v3.0.0 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.

5.9 CONCLUSIONS

The proposed device, LungQ v3.0.0, 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.