Thirona Corporation
℅ Jean-Paul Charbonnier
Managing Director
Toernooiveld 300
6525 EC Nijmegen
THE NETHERLANDS

June 5th , 2018

Re: K173821
Trade/Device Name: LungQ
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 31, 2018
Received: June 1, 2018

Dear Jean-Paul Charbonnier:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K173821

Device Name
LungQ

Indications for Use *(Describe)*

The Thirona LungQ software provides CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis and follow up examination. The Lung Q 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.**

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

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## Section 2.0 510(k) Summary

| | |
|---|---|
| **Submitter** | Thirona Corporation |
| **Contact Person** | Eva van Rikxoort<br>Managing Director<br>Thirona BV<br>Toernooiveld 300<br>6525 EC Nijmegen<br>the Netherlands<br>Phone: +31 (0)647142838<br>E-mail: evavanrikxoort@thirona.eu |
| **Date Prepared** | June X, 2018 |
| **Trade Name** | LungQ |
| **Common Use/Usual Name** | Computer Tomography X-ray system |
| **Product Code** | JAK |
| **Classification** | Class II, 21 CFR 892.1750 |
| **Device Panel** | Radiology |
| **Predicate Device** | VIDA PW2 |
| **Predicate Classification** | Class II, 21 CFR 892.1750 |
| **Reference Device** | Imbio CT Lung Density Analysis Software |
| **Reference Classification** | Class II, 21 CFR 892.1750 |

**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.

**Indications for Use**

The Thirona LungQ software provides 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.

**Summary of Technical Comparisons**
The table below compares the Thirona LungQ software to both the predicate and reference devices.

| Item | LungQ<br>Thirona<br>(Subject Device) | VIDA PW2<br>VIDA Diagnostics<br>K083227<br>(Predicate Device) | Imbio CT Lung Density Analysis Software<br>Imbio LLC<br>K141069<br>(Reference Device) |
|---|---|---|---|
| **Product Code** | JAK | Identical | Identical |
| **Regulation Number** | 21 CFR 892.1750 | Identical | Identical |
| **Device Classification** | Class II | Identical | Identical |
| **Common Name** | Software Accessory to a Computed tomography x-ray system | Identical | Identical |

| Item | LungQ<br>Thirona<br>(Subject Device) | VIDA PW2<br>VIDA Diagnostics<br>K083227<br>(Predicate Device) | Imbio CT Lung Density Analysis Software<br>Imbio LLC<br>K141069<br>(Reference Device) |
|---|---|---|---|
| **Intended Use** | The Thirona LungQ software provides 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. | Nearly Identical | Nearly Identical |
| **Modality** | CT | Identical | Identical |
| **Data Loading** | DICOM | Identical | Identical |
| **Application** | Command-line interface | Includes a workstation | Identical |
| **Segmentation** | Provides 3D segmentation | Identical | Identical |

| Item | LungQ Thirona (Subject Device) | VIDA PW2 VIDA Diagnostics K083227 (Predicate Device) | Imbio CT Lung Density Analysis Software Imbio LLC K141069 (Reference Device) |
|---|---|---|---|
| | Provides Segmentation of the:<br>• Left Lung<br>• Right Lung<br>• Left Upper Lobe<br>• Left Lower Lobe<br>• Right Upper Lobe<br>• Right Middle Lobe<br>• Right Lower Lobe | Identical | Similar |
| | Provides Airways Segmentation | Identical | Different |
| | User cannot manually edit segmentation | User can manually edit segmentation | Identical |
| **Lung Volume Analysis Support** | Ability to measure volume for:<br>• Both Lungs<br>• Left Lung<br>• Right Lung<br>• Left Upper Lobe<br>• Left Lower Lobe<br>• Right Upper Lobe<br>• Right Middle Lob<br>• Right Lower Lobe | Identical | Similar |

| Item | LungQ Thirona (Subject Device) | VIDA PW2 VIDA Diagnostics K083227 (Predicate Device) | Imbio CT Lung Density Analysis Software Imbio LLC K141069 (Reference Device) |
|---|---|---|---|
| **Volume Density Analysis** | Ability to measure volume at multiple density ranges for:<br>• Both Lungs<br>• Left Lung<br>• Right Lung<br>• Left Upper Lobe<br>• Left Lower Lobe<br>• Right Upper Lobe<br>• Right Middle Lob<br>• Right Lower Lobe | Identical | Similar |
| | Ability to measure the 15$^{th}$ percentile density analysis | Identical | Different |
| | Does not perform low density cluster analysis | Does perform low density cluster analysis | Identical |
| **Fissure Analysis** | Ability to perform fissure evaluations | Identical | Does not perform fissure evaluations |
| **Analyzed Data Output** | Provides a report | Identical | Identical |

**Non-Clinical 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 implantation and system integration testing. The LungQ software successful 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.

An equivalence study comparing 250 CT scans from the COPDGene study (http://www.copdgene.org) analyzed by the predicate device, VIDA PW2, and the same 250 CT scans analyzed by Thirona LungQ. LungQ 1.1.0 was run allowing for interaction with the LungQ results in the Image Analysis Service as described in the Service Manual. The scans were randomly selected from the entire COPDGene cohort, leading to a population of subjects with and without COPD and with different stages of COPD. The distribution of subjects with respect to their disease state is provided below.

| **Category** | **Disease state** | **# of subjects** | **% of data set** |
|---|---|---|---|
| Control subjects: current or former smokers without airflow limitation | GOLD stage 0 | 112 | 44.80% |
| Subjects with COPD but with minimal airflow limitations | GOLD stage 1 | 26 | 10.40% |
| Subjects with COPD and with moderate to severe airflow limitations | GOLD stage 2-4 | 76 | 30.40% |
| Subjects with preserved ratio but impaired spirometry | GOLD stage PRISm | 33 | 13.20% |
| Control subjects: non-smokers | None | 3 | 1.20% |

The 250 scans were taken with a wide variety of scanners. The imaging parameters of the 250 scans are provided below.

The outputs between VIDA PW2 and Thirona LungQ 1.1.0 were compared. The following measurements were analyzed for equivalence:

- Lung and lobar volumes
- Lung and lobar density scores:
  - Low attenuation areas below -950 HU (LAA-950HU)
  - Low attenuation areas below -910 HU (LAA-910HU)
  - $15^{th}$ percentile of density histogram (perc15)

Equivalence was determined using the following criteria:

- Lung and lobar volume: Difference $\leq$ 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

The results showed that outputs from Thirona LungQ 1.1.0 are equivalent to the predicate device, VIDA PW2.

Additional performance testing of Thirona LungQ fissure analysis was conducted to compare a previously published version to LungQ 1.1.0. This study was performed on a set of 55 scans taken from a multicentre study conducted at five clinical study sites located in Germany, the Netherlands and Sweden (NCT01101958). The 55 scans were taken with a wide variety of scanners. The imaging parameters of the 55 scans are provided below.

Voxel-wise fissure completeness was compared to a manual reference standard in order to evaluate the performance of the two algorithms. The area under the receiver operating characteristic curve (Az) was used as a performance measure. A statistically higher Az value was set as the criteria to prove that LungQ 1.1.0 outperforms the previously published version.

For each individual scan, the Az value for LungQ 1.1.0 was higher compared to the previously published version. The average Az of LungQ 1.1.0 was 0.95, compared to a statistically significantly lower average Az value of 0.76 for the previously published version (tested with a paired-sample t-test, $p<0.001$). This study showed that the fissure analysis of LungQ 1.1.0 significantly outperforms the previously published version.

| **Imaging parameters** | **Equivalence study** | **Fissure analysis** |
|---|---|---|
| # of scans | 250 | 55 |
| Voxel spacing | 0.50 - 0.97 mm | 0.44 - 0.81 mm |
| Slice thickness | 0.625 - 0.9 mm | 0.6 - 1.5 mm |
| Slice spacing | 0.45 - 0.625 mm | 0.45 - 1.2 mm |
| Peak Kilovoltage | 120 pKv | 120 - 130 pKv |
| Scanner manufacture | GE MEDICAL SYSTEMS; SIEMENS; Philips | 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 | Mx8000 IDT 16; iCT 128; Volume Zoom; Emotion 16; Sensation 64; Definition; SOMATOM Definition; |
| Reconstruction algorithms | Filtered back projection | Filtered back projection |
| Reconstruction kernels | STANDARD; B35f; B | B40f; B50s; B60f; B60s; B80f |
| milliampere second | 200 mAs | NA |

**Conclusions**

Based on the comparison of intended use and key technological characteristics, Thirona believes that the Subject Device (LungQ) is substantially equivalent to the Predicate Device.