September 2, 2021

Pulmonx Corporation
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K212494
Trade/Device Name: Lung Image Analysis (LIA)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 6, 2021
Received: August 9, 2021

Dear Prithul Bom:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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.

Submission Number *(if known)*

K212494

Device Name

Lung Image Analysis (LIA)

Indications for Use *(Describe)*

The Pulmonx LIA software provides CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis and follow up examination. The LIA software can be used to support physician in the diagnosis and documentation of pulmonary tissue images (e.g. abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments (including lung structures), 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.

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510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant Information:

Pulmonx Corporation
700 Chesapeake Drive
Redwood City, California 94063

Contact Person:

Terry Solomon
Email: tsolomon@pulmonx.com
Phone: (650) 216-0195

Device Information:

Trade Name:	Lung Image Analysis (LIA)
Regulation Name:	Computed tomography x-ray system
Regulation Medical Specialty:	Radiology
Device Class:	II
Product Code:	JAK

Predicate Device:

LungQ, K173821
The predicate device has not been subject to a design-related recall.

No reference device is being used in this submission.

Date Prepared:

June 30, 2021

Device Description:

The Lung Image Analysis (LIA) software is designed to aid in the interpretation of Computed Tomography (CT) scans of the thorax that may contain pulmonary abnormalities. Lung Image Analysis has both a graphical user interface and command-line software which can be run as a Windows application or from a command-line interpreter. The LIA software is to be used by trained professionals who are responsible for the correct and accurate use of medical images. In a typical clinical environment, the results provided by the software are used together with other clinical information by a medical professional.

The software may be installed on an off-the-shelf PC computer system and is intended to be used with uncompressed digital images that are saved in DICOM format.

Indications for Use:

The LIA software provides CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis and follow up examination. The LIA software can be used to support physician in the diagnosis and documentation of pulmonary tissue images (e.g. abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments (including lung structures), volumetric analysis, density evaluations, fissure evaluation, and reporting tools are provided.

Summary of Technical Comparison:

The LIA software is comparative to the predicate device, the Thirona LungQ Software (see Table 1). The software has the same intended use and similar technological characteristics, which do not raise any new questions of safety or effectiveness.

Table 1: Substantial Equivalence between LIA and LungQ, the predicate device.

Item	LIA Pulmonx (Subject Device)	LungQ Thirona K173821 (Predicate Device)	Equivalence
Product Code	JAK	JAK	Yes, identical.
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	Yes, identical.
Device Classification	Class II	Class II	Yes, identical.
Common Name	Software Accessory to a Computed tomography x-ray system	Software Accessory to a Computed tomography x-ray system	Yes, identical.
Intended Use	The LIA software provides CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis and follow up examination. The LIA software can be used to support physician in the diagnosis and documentation of pulmonary tissue images (e.g. abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments (including lung structures), volumetric analysis, density evaluations, fissure evaluation, and reporting tools are provided.	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 tissue 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.	Yes, identical.
Modality	CT	CT	Yes, identical.
Data Loading	DICOM	DICOM	Yes, identical.
Application	Graphical User Interface and	Command-line interface	Yes, both devices provide

Item	LIA Pulmonx (Subject Device)	LungQ Thirona K173821 (Predicate Device)	Equivalence
	Command-line interface		a command-line interface while the subject device also provides a GUI. The addition of the GUI provides a more user-friendly interface.
Segmentation	Provides 3D segmentation	Provides 3D segmentation	Yes, identical.
	Provides segmentation of the: Left Lung Right Lung Left Upper Lobe Left Lower Lobe Right Upper Lobe Right Middle Lobe Right Lower Lobe	Provides segmentation of the: Left Lung Right Lung Left Upper Lobe Left Lower Lobe Right Upper Lobe Right Middle Lobe Right Lower Lobe	Yes, identical.
	Provides Airways Segmentation	Provides Airways Segmentation	Yes, identical.
	Software automatically calculates segmentation (i.e. lobe boundaries) and user can manually edit lobe boundaries	Software automatically calculates segmentation.	Yes, both devices automatically calculate segmentation. The subject device also allows the user to manually edit segmentation. Manually editing segmentation was included as a feature for cases where the lobe boundaries may be difficult to automatically segment.
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 Lobe Right Lower Lobe	Ability to measure volume for: Both Lungs Left Lung Right Lung Left Upper Lobe Left Lower Lobe Right Upper Lobe Right Middle Lobe Right Lower Lobe	Yes, identical.
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 Lobe	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 Lobe	Yes, identical.

Item	LIA Pulmonx (Subject Device)	LungQ Thirona K173821 (Predicate Device)	Equivalence
	Right Lower Lobe	Right Lower Lobe	
	Allows the user to perform the 15th percentile density analysis	Software provides the 15th percentile density analysis	Yes, the output provides histogram data that this can be calculated from.
Fissure Analysis	Ability to perform fissure evaluations	Ability to perform fissure evaluations	Yes, identical.
Analyzed Data Output	Provides data in .csv or .json file	Provides a report	Yes, both devices provide output to be used by physicians.

Performance Data:

Software verification and validation (V&V) were conducted to ensure that the LIA software met its intended use and software requirements. The V&V testing included subsystem integration testing, unit testing, module testing, and code reviews. The Lung Image Analysis software successfully passed the verification and validation.

An equivalence study was conducted to compare data from 30 scans that were analyzed by both the predicate device, Thirona LungQ, and the subject device, Lung Image Analysis. Each device computed 120 fissure calculations, 180 lobar volumes, and 360 voxel density scores from 30 scans. Results from the two devices were similar, meeting the acceptance criteria. This shows that the Lung Image Analysis software is equivalent in performance to the predicate device.

Summary:

The LIA software has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness.