March 4, 2020

Fluidda Inc.
c/o Anjali Nair
Regulatory Affairs Specialist
750 N. San Vicente Blvd, Suite 800 West
WEST HOLLYWOOD CA 90069

Re: K191550
Trade/Device Name: Broncholab
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: January 28, 2020
Received: January 29, 2020

Dear Anjali Nair:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191550

Device Name
Broncholab

Indications for Use *(Describe)*
Broncholab provides physicians with reproducible CT values for pulmonary tissue for providing quantitative support for diagnosis and follow-up examination. Broncholab 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 subcompartments, volumetric analysis, density evaluations, low density cluster analysis, fissure evaluation and reporting tools are combined with a dedicated workflow.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 - 510(k) Summary

Submitter	Fluidda Inc.
Submission Number	K191550
Address	750 N San Vicente Blvd Ste. 800 West, West Hollywood, CA 90069, USA
Contact Person	Anjali Nair Regulatory Affairs Specialist at Fluidda Inc. Tel: +91 9324857705 Email: anjali.nair@fluidda.com
Date Prepared	January 28, 2020
Trade Name	Broncholab
Common Name	Quantitative CT analysis system
Classification Name	Computed Tomography X-Ray System
Regulation Number	21 CFR 892.1750
Classification	Class II
Product Code	JAK
Panel	Radiology
Legally marketed Primary Predicate Device	Vida Pulmonary Workstation 2 (PW2), Vida Diagnostics (K083227)
Predicate Regulation Number	21 CFR 892.1750
Predicate Classification & Product Code	Class II; Product Code- JAK The predicate device has not been subject to a design-related recall.

Device Description

Broncholab is a SaMD (Software as Medical Device) which provides quantitative CT values that are intended to support the physician in the diagnosis and documentation of pulmonary tissues images (abnormalities) from CT scans. The CT scan images are transformed into 3D models of the patient-specific lungs using several image processing steps. Broncholab can be used to assess the effectiveness of therapy based on CT scan data. It is used along with the following accessories:

- Web Portal: Enables the uploading of CT scans and patient data
- Client Report: Enables the conversion of the output of Broncholab (CT values) into a desired digital format (PDF Report) and transfers this Report to the physician via email.

Inspiratory CT scan images uploaded by the users are converted into quantitative CT values using a combination of software tools. Quality checks (both manual and automated) are implemented to assure the quality of the final data. The outputs are provided as absolute values and as a percentage of the total airway volume/ lung volume/ lobar volume depending on the parameter. The device can be used on a computer with a web browser installed and consists of two accessories:

- An online portal to upload the CT scans
- An accessory that enables the creation of the Report

The CT values include:

1. **Lung and Lobar Volume** is the volume of the 3D model of each lung lobe.
2. **Airway Volume** is defined as the region from the trachea until the segmental bronchi.
3. **Lung Density Scores/ Volumes** is defined as all the intrapulmonary voxels with Hounsfield Units between -1024 and -950 using the inspiratory scans:
    - Low attenuation areas below -950 HU (LAA-950HU)
    - 15th percentile of density histogram : Percentile density (PD) can also be used to express Emphysema.
    - Blood vessel density : Blood vessel density can be determined through segmentation and 3-D reconstruction of the blood vessels. The segmentation is based on local geometry features and HU thresholds and is performed on the inspiratory CT scan.
4. **Fissure Analysis (fissure integrity)** is the percentage of completeness of the fissure. Lung fissures are a double-fold of visceral pleura that either completely or incompletely separates the lungs into lung lobes.

CT scan images must be DICOM 3.0 compliant.

Indications for Use Statement

Broncholab provides physicians with reproducible CT values for pulmonary tissue for providing quantitative support for diagnosis and follow-up examination. Broncholab 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 subcompartments, volumetric analysis, density evaluations, low density cluster analysis, fissure evaluation and reporting tools are combined with a dedicated workflow.

Summary of Technological Comparisons

		Subject Device	Predicate Device	SUBSTANTIAL EQUIVALENCE (SE) COMPARISON
Device Proprietary Name		Broncholab	Vida Pulmonary Workstation 2 (PW2)	
Manufacturer		Fluidda, Inc.	Vida Diagnostics	
510(k)		K191550	K083227	
Labeling				
Classification	**Regulation**	21 CFR 892.1750	21 CFR 892.1750	Same
	Product code	JAK	JAK	Same
	Class. Name	Computed Tomography X- Ray System	Computed Tomography X- Ray System	Same
Indications for Use Statement		Broncholab provides physicians with reproducible CT values for pulmonary tissue for providing quantitative support for diagnosis and follow-up examination.	The Vida Pulmonary Workstation 2 (PW2) software provides reproducible CT values for pulmonary tissue which is essential for providing quantitative support for diagnosis and follow up examinations.	Same
		Broncholab can be used to support physicians in the diagnosis and documentation of pulmonary tissues images (e.g., abnormalities) from CT thoracic datasets.	The PW2 can be used to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from CT thoracic datasets.	Same
		Three-D segmentation and isolation of subcompartments, volumetric analysis, density evaluations, low density cluster analysis, fissure evaluation and reporting tools are combined with a dedicated workflow.	Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, low density cluster analysis and reporting tools are combined with a dedicated workflow.	Same
Intended User Population		Physician	Physician	Same
Patients population		Broncholab can be used to support physicians in the diagnosis and documentation of pulmonary tissues images (e.g., abnormalities) from CT thoracic datasets.	The PW2 can be used to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from CT thoracic datasets.	Same

	Subject Device	Predicate Device	SUBSTANTIAL EQUIVALENCE (SE) COMPARISON
Device Proprietary Name	Broncholab	Vida Pulmonary Workstation 2 (PW2)	
Manufacturer	Fluidda, Inc.	Vida Diagnostics	
510(k)	K191550	K083227	
Technical (IT) Considerations			
Modality	CT	CT	Same
Data Loading	DICOM	DICOM	Same
Application	Graphical User Interface (GUI)	Workstation	Equivalent Using the GUI does not affect the processing of scans. It only provides a means to transfer the input and receive the output (Report). These differences do not raise different questions regarding the safety and effectiveness of the subject device.
Automation of process	Automation of tasks within the workflow of the FRI Quantification Software	Fully automated analysis of an inspiratory chest CT scan	Equivalent
Software device that operates on industry standard hardware	Yes	Yes	Same
CT Scan Protocol Requirements	Equivalent	Equivalent	Equivalent
Input	Chest CT Scans	Chest CT Scans	Same
Output	1. Lung and lobar volume 2. Airway volume 3. Lung and lobar density scores 4. Fissure analysis	1. Lung and lobar volume 2. Lung and lobar density scores 3. Fissure analysis	Like the predicate, the subject device provides: 1. Lung and lobar volume 2. Lung and lobar density scores 3. Fissure analysis Performance testing to demonstrate accuracy and effectiveness of the airway volume and blood vessel density parameter, along with all other outputs has been performed and the results are placed in **Section 18 - Performance Testing - Bench**.
Analyzed Data Output	Provides a Report	Provides a report	Same

		Subject Device	Predicate Device	SUBSTANTIAL EQUIVALENCE (SE) COMPARISON
Device Proprietary Name		Broncholab	Vida Pulmonary Workstation 2 (PW2)	
Manufacturer		Fluidda, Inc.	Vida Diagnostics	
510(k)		K191550	K083227	
Tasks performed by Device				
	Segmentation	Provides Three-D Segmentation	Provides Three-D Segmentation	Same
		Provides Segmentation of: • Left Lung • Right Lung • Left Upper Lobe (LUL) • Left Lower Lobe (LLL) • Right Upper Lobe (RUL) • Right Middle Lobe (RML) • Right Lower Lobe (RLL)	Provides Segmentation of: • Left Lung • Right Lung • Left Upper Lobe (LUL) • Left Lower Lobe (LLL) • Right Upper Lobe (RUL) • Right Middle Lobe (RML) • Right Lower Lobe (RLL)	Same
		Provides Airway Segmentation	Provides Airway Segmentation	Same
		Intended user cannot manually edit segmentation.	Intended user can manually edit segmentation	These differences do not raise different questions regarding the safety and effectiveness of the subject device.
	Volumetric Analysis	Ability to measure volume for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe (LUL) • Left Lower Lobe (LLL) • Right Upper Lobe (RUL) • Right Middle Lobe (RML) • Right Lower Lobe (RLL)	Ability to measure volume for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe (LUL) • Left Lower Lobe (LLL) • Right Upper Lobe (RUL) • Right Middle Lobe (RML) • Right Lower Lobe (RLL)	Same
	Density analysis	Ability to measure volume at multiple density ranges for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe (LUL) • Left Lower Lobe (LLL) • Right Upper Lobe (RUL) • Right Middle Lobe (RML) • Right Lower Lobe (RLL)	Ability to measure volume at multiple density ranges for: • Both Lungs • Left Lung • Right Lung • Left Upper Lobe (LUL) • Left Lower Lobe (LLL) • Right Upper Lobe (RUL) • Right Middle Lobe (RML) • Right Lower Lobe (RLL)	Same
		Ability to measure 15th percentile density, blood vessel density and perform fissure evaluations	Ability to measure 15th percentile density, blood vessel density and perform fissure evaluations	Same
	Detects Airway Morphology	Yes	Yes	Same
Steps in the use of the device				

Steps in the use of the device				
	Quality check of CT Scans	Quality Checks on CT Scans	Integrated scan quality check	Equivalent Both the subject and predicate devices conduct quality checks on incoming data although exact wording is different.
	Analysis	Automation of tasks in the workflow of the FRI Quantification Software.	Fully automated quantification	Equivalent In the case of both the devices, image processing steps that can be done manually are done automatically in order to save time. Any differences do not raise different questions regarding the safety and effectiveness of the subject device.
	Review of output	The Report is QC verified before it is emailed to the physician.	Automated quality check of the Report	Equivalent In the case of both the subject and the predicate devices, the final output is reviewed before it is made available to the intended user.
	Delivery of results: the results are delivered back to the intended user	Yes	Yes	Same
Other Areas of Comparison				
	Energy used and/or delivered to patient	No	No	Same
	Materials	N/A	N/A	Same
	Biocompatibility	N/A	N/A	Same

Non-Clinical Performance Testing

Verification testing was conducted against predetermined acceptance criteria to show that the subject device performs the functions that are equivalent to the predicate device. Broncholab successfully passed verification testing. Design validation was performed in simulated use settings. The results support substantial equivalence of the subject device to the predicate device and demonstrate that it is safe and effective for its intended use.

The following quality assurance measures were applied during software development:

- Software Development Life Cycle
- Software Risk Assessment
- Software Configuration Management and Version Control
- Software issue tracking and resolution

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 at inspiration, such as lobe volume, emphysema, blood vessel density, 15th percentile lung density (PD15) and fissure integrity, between the Broncholab device and the VIDA device, i.e. primary predicate (K083227). Firstly, both devices analyzed the lobe volume, emphysema, blood vessel density, PD15 and fissure integrity. Subsequently, Bland-Altman plots were used for the pairwise comparison of the lobe volume, emphysema, blood vessel density and PD15 measurements between the two devices. Moreover, for the comparison of the fissure integrity measurements between both devices, the Intraclass Correlation Coefficient (ICC) with 95% confidence interval (CI) was calculated. The airway volumes are not compared with the primary predicate but with segmentations which were corrected by three physicians. The pairwise comparison between Broncholab and the physicians was performed using Bland-Altman plots of airway volume.

The tolerable variability for absolute and relative values are 150mL and 5%, respectively.

The results showed that for the lobe volume, emphysema and blood vessel density measurements expressed in relative values, the mean differences (range) between Broncholab and the primary predicate were all less than 5%. When expressed in absolute values, the mean differences (range) between Broncholab and the primary predicate were less than the threshold absolute value. The mean difference (range) between Broncholab and the primary predicate for the PD15 measurements was less than 1 HU. The ICC estimate (95% CI) for comparison of the fissure integrity measurements between Broncholab and the primary predicate was found to be 0.75 (0.54, 0.87). The mean difference (range) between Broncholab and the physicians for the airway volume measurements expressed in relative values was less than 5%. Expressed in absolute values the mean difference (range) was less than the absolute threshold value. Ground truth was established by taking the mean airway volume obtained from three physicians' segmentation.

The scans were take with a wide variety of scanners. The CT scanner brands and models used to obtain scans in the datasets used for the performance testing are:

Imaging parameters	**Equivalence study**
Scanner manufacture	GE Healthcare; Philips; Siemens
Scanner types	LightSpeed VCT; LightSpeed Pro 16; LightSpeed 16; Revolution CT; Revolution EVO; iCT 256; Emotion 16; SOMATOM Definition AS; SOMATOM Force; SOMATOM Definition Flash; Brilliance 64; Definition; Definition AS+; Discovery CT750 HD; Sensation 64

Clinical Performance Data

No clinical performance testing data is provided with this submission.

Conclusion

Based on the intended use and technological characteristics comparison, non-clinical tests described, it can be concluded that taken individually as well as in sum, the subject device (Broncholab) is as safe, as effective, and performs as well as the predicate device (Vida PW2) and is thus substantially equivalent to it.