DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Vital Images, Inc.
% Ms. Katie Ryan
Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343-4414

October 10, 2015

Re: K151919
Trade/Device Name: Vitrea® CT Lung Density Analysis Software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 18, 2015
Received: September 21, 2015

Dear Ms. Ryan:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151919

Device Name
Vitrea® CT Lung Density Analysis Software

Indications for Use *(Describe)*
The Vitrea Lung Density Analysis software provides CT values for the pulmonary tissue from CT thoracic datasets. Three-dimensional (3D) segmentation of the left lung and right lung, volumetric analysis, density evaluations and reporting tools are integrated in a specific workflow to offer the physician a quantitative support for diagnosis and follow-up evaluation of lung tissue images.

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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510K Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92(c).

Basis for the Submission:	To obtain 510k clearance for Vital's software preset Vitrea CT Lung Density Analysis which is substantially equivalent to the cleared VIDA Pulmonary Workstation 2 (PW2) manufactured by VIDA Diagnostics.
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Katie Ryan Regulatory Affairs Specialist Phone : 952–487–9793 Fax: 952–487–9510 E-mail: kryan@vitalimages.com
510(k) Type:	Traditional
Summary Date:	July 20, 2015
Device Trade Name:	Vitrea® CT Lung Density Analysis Software
Device Common Name/ Regulatory Description:	Computed Tomography X-ray System
Device Classification Name:	System, X-ray, Tomography, Computed
Regulation Number:	21 CFR 892.1750
Product Code:	JAK
Regulatory Classification:	Class II
Device Panel:	Radiology

Predicate Device(s):

Predicate Device	Manufacturer	FDA 510(k) Number
VIDA Pulmonary Workstation 2 (PW2)	VIDA Diagnostics 100 Oakdale Campus, Suite 225 Tic Iowa City, IA 55242	K083227

Reference Device(s):

Reference Device	Manufacturer	FDA 510(k) Number
VITREA2, Version 3.7 Medical Image Processing System (Lung Analysis)	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN 55343	K043333

Device Description:
Vitrea CT Lung Density Analysis assists in analyzing lung densities and volumes. It semi-automatically segments lung tissues with quantifiable controls and renderings to aid communication with the pulmonologist.

The key features are:

- Semi-automatic right lung, left lung, and airway segmentation
- Visualization of lung density with color-defined Hounsfield Unit (HU) ranges
- Lung density result quantification with HU density range, volume measurements, lung density index, and the PD15% measurement
- Density graph/histogram of the classified lung voxels' relative frequencies
- Comparison of upper and lower lung density index ratios
- Adjustable density thresholds for refining and optimizing HU ranges
- Overlay of density quantification results and density graph histogram for reporting
- Export of density values and curves to CSV tables or copy to clipboard for insertion into a report

Intended Use / Indications for Use:
The Vitrea Lung Density Analysis software provides CT values for the pulmonary tissue from CT thoracic datasets. Three-dimensional (3D) segmentation of the left lung and right lung, volumetric analysis, density evaluations and reporting tools are integrated in a specific workflow to offer the physician a quantitative support for diagnosis and follow-up evaluation of lung tissue images.

Intended for Disease / Condition / Patient Population:
The software provides Thoracic Radiologists and Pulmonologists with a robust dedicated suite of software tools to aid in the creation of evidence to support these physicians with their assessment of patients with chest diseases.

Substantial Equivalence Comparison:

Regulatory Comparison

Characteristic	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	VIDA Pulmonary Workstation 2 (PW2)	
Classification Name	Computed Tomography X-ray System.	Computed Tomography X-ray System.	None
Regulatory Number	892.1750	892.1750	None
Product Code	JAK	JAK	None
Classification	Class II	Class II	None
Review Panel	Radiology	Radiology	None
Decision Date	Under Review	November 8, 2008	Predicate and Reference devices are cleared

Intended Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	VIDA Pulmonary Workstation 2 (PW2)	
Intended Use	The Vitrea Lung Density Analysis software provides CT values for the pulmonary tissue from CT thoracic datasets. Three-dimensional (3D) segmentation of the left lung and right lung, volumetric analysis, density evaluations and reporting tools are integrated in a specific workflow to offer the physician a quantitative support for diagnosis and follow-up evaluation of lung tissue images.	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. 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. Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, low density cluster analysis and reporting tools are	The support for low density cluster analysis is not part of the subject device's indications for use.

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	**VIDA Pulmonary Workstation 2 (PW2)**	
		combined with a dedicated workflow. The VIDA Pulmonary Workstation 2 (PW2) software package is also intended to be a real-time interactive evaluation in space and time for CT volume data sets that provides the reconstruction of two-dimensional images into a three-dimensional image format.	
Intended Users	Thoracic Radiologists and Pulmonologists	Thoracic Radiologists and Pulmonologists	None
Patient Population	Patients with pulmonary diseases and abnormalities	Patients with chest diseases, e.g. when examining the pulmonary tissue (i.e. lung parenchyma) in CT thoracic datasets	Similar
Modality Support	CT /CTA	CT /CTA	None

Device Description Comparison with Predicate Device:

Subject Device	Predicate Device	Comparison
Vitrea CT Lung Density Analysis Software	**VIDA Pulmonary Workstation 2 (PW2)**	
Vitrea CT Lung Density Analysis assists in analyzing lung densities and volumes. It semi-automatically segments lung tissues with quantifiable controls and renderings to aid communication with the pulmonologist. <u>The key features are:</u> • Semi-automatic right lung, left lung and airway segmentation • Visualization of lung density with color-defined Hounsfield Unit (HU) ranges • Lung density result quantification with HU density range, volume measurements, lung density index and the PD15% measurement • Density graph/histogram of the classified lung voxels' relative frequencies • Comparison of upper and lower lung density index ratios • Adjustable density thresholds for refining and optimizing HU ranges • Overlay of density quantification results and density graph histogram for reporting • Export of density values and curves to CSV tables or copy to clipboard for insertion into a report	VIDA Pulmonary Workstation 2 *(PW2)* is a self-contained image analysis software package. This real-time interactive evaluation in space and time for CT volume data sets provides the reconstruction of two-dimensional images into a three-dimensional image format. VIDA Pulmonary Workstation 2 (PW2) can be used to support the physician in the diagnosis and documentation of chest diseases, e.g. when examining the pulmonary tissue (i.e. lung parenchyma) in CT thoracic datasets. Evaluation tools (3D segmentation & isolation of sub-compartments, volumetric analysis, density evaluations, and low density cluster analysis) and reporting tools are combined with a dedicated workflow. The PW2 is designed to analyze pulmonary CT slice data and display analysis results. Each voxel of the scan is measured by Hounsfield units (HU), a measurement of x-ray attenuation that is applied to each volume element in three-dimensional space ("voxel"). The HU are utilized to distinguish between air, water, tissue and bone, such distinction is common in the industry. *PW2* provides computed tomography (CT) viewing, airway analysis, and parenchymal density analysis in one application. *PW2* provides imaging of bronchial airways that can be used to assess therapy effectiveness based on CT scan data. *PW2* reconstructs multiple cross-section images from CT data into a computer model displaying complex bronchial branches. *PW2* does not interface directly with any CT or data collection equipment; instead *PW2* imports data files previously generated by such equipment. PW2 provides quantitative measurements and tabulates quantitative properties. PW2 focuses on what is visible to the eye and applies volumetric methods that might otherwise be too tedious to use. The software does not perform any function	The support for low density cluster analysis is not part of the subject device description.

Subject Device	Predicate Device	Comparison
Vitrea CT Lung Density Analysis Software	**VIDA Pulmonary Workstation 2 (PW2)**	
	which cannot be accomplished by a trained user utilizing manual tracing methods; the intent of the software is to save time and automate potential error prone manual tasks. The software has functions for loading, analyzing, saving datasets and will generate screen displays, computations and aggregate statistics.	

Similarities in Technology with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	**VIDA Pulmonary Workstation 2 (PW2)**	
Modality			
CT	Yes	Yes	Same
Data Loading			
DICOM	Yes	Yes	Same
Ability to load one or two series of chest CT exam	Yes	Yes	Same
Data Viewing Support			
MPR	Yes	Yes	Same
3D	Yes	Yes	Same
Segmentation			
Provides 3D Segmentation tool	Yes	Yes	Same
Provide Left Lung Segmentation	Yes	Yes	Same
Provides Right Lung Segmentation	Yes	Yes	Same
Provides airways segmentation (trachea, main bronchi, and some larger bronchioles)	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	VIDA Pulmonary Workstation 2 (PW2)	
User can manually edit segmentation provided by the software	Yes	Yes	Same
Lung Volume Analysis Support			
Ability to measure and view Left Lung volume	Yes	Yes	Same
Ability to measure and view Right Lung volume	Yes	Yes	Same
Lung Density Analysis Support			
Low (ml) Volume for Right Lung: Ability to measure volume of Right lung voxels in the lowest HU density range as defined by the density thresholds	Yes	Yes	Same
Low (ml) Volume for Left Lung: Ability to measure volume of Left lung voxels in the lowest HU density range as defined by the density thresholds	Yes	Yes	Same
Low (ml) Volume for Both Lungs: Ability to measure addition of volumes of both lungs voxels in the lowest HU density range as defined by the density thresholds	Yes	Yes	Same
Medium (ml) Volume for Right Lung: Ability to measure volume of Right lung voxels in the middle HU density range as defined by the density thresholds	Yes	Yes	Same
Medium (ml) Volume for Left Lung:	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	VIDA Pulmonary Workstation 2 (PW2)	
Ability to measure volume of Left lung voxels in the middle HU density range as defined by the density thresholds			
Medium (ml) Volume for Both Lungs: Ability to measure addition of volumes of both lungs voxels in the middle HU density range as defined by the density thresholds	Yes	Yes	Same
High (ml) Volume for Right Lung: Ability to measure volume of Right lung voxels in the highest HU density range (such as vessels) as defined by the density thresholds	Yes	Yes	Same
High (ml) Volume for Left Lung: Ability to measure volume of Left lung voxels in the highest HU density range (such as vessels) as defined by the density thresholds	Yes	Yes	Same
High (ml) Volume for Both Lungs: Ability to measure addition of volumes of both lungs voxels in the highest HU density range (such as vessels) as defined by the density thresholds	Yes	Yes	Same
Right Lung (ml) Volume: Ability to provide Right lung volume including only the voxels designated as Low and Medium Right	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	**VIDA Pulmonary Workstation 2 (PW2)**	
lung tissues			
Left Lung (ml) Volume: Ability to provide Left lung volume including only the voxels designated as Low and Medium Left lung tissues	Yes	Yes	Same
Lung (ml) Volume: Ability to provide addition of both lungs volumes including only the voxels designated as Low and Medium Right and Left lung tissues	Yes	Yes	Same
Low Density (LD) Index (%) for Right Lung: $\frac{\text{Low Right Lung volume}}{(\text{Low Right Lung volume} + \text{Medium Right Lung volume})}$	Yes	Yes	Same
Low Density (LD) Index (%) for Left Lung: $\frac{\text{Low Left Lung volume}}{(\text{Low Left Lung volume} + \text{Medium Left Lung volume})}$	Yes	Yes	Same
Low Density (LD) Index (%) for Both Lungs:	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	**VIDA Pulmonary Workstation 2 (PW2)**	
$\frac{\text{Addition of Left and Right Lungs Low volumes}}{(\text{Addition of Left and Right Lungs Low volumes} + \text{Addition of Left and Right Lungs Medium volumes})}$			
PD15 (g/l) measurement for Right Lung: The HU value which a certain percentage (15%) of the voxels in the cumulative frequency distribution histogram have a lower density in Right Lung	Yes	Yes	Same
PD15 (g/l) measurement for Left Lung: The HU value which a certain percentage (15%) of the voxels in the cumulative frequency distribution histogram have a lower density in Left Lung	Yes	Yes	Same
PD15 (g/l) measurement for Both Lungs: The HU value which a certain percentage (15%) of the voxels in the frequency distribution histogram have a lower density in both Lungs	Yes	Yes	Same
Ability to generate Density graphs	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	VIDA Pulmonary Workstation 2 (PW2)	
Analyzed Data Export			
Ability to take snapshot	Yes	Yes	Same
Ability to generate report	Yes	Yes	Same

Differences in Technology with the Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Lung Density Analysis Software	VIDA Pulmonary Workstation 2 (PW2)	
Low density cluster analysis	No	Yes	The support for low density cluster analysis is not part of the subject device.

Similarities in Technology with the Reference Device:

Criteria	Subject Device	Reference Device	Comparison
	Vitrea CT Lung Density Analysis Software	VITREA2, Version 3.7 Medical Image Processing System (Lung Analysis)	
Segmentation	Yes	Yes	Similar Note: The Lung Analysis preset shows lung segmentation as a single region while the CT Lung Density Analysis preset provides left and right lung regions. The sum of left and right lung regions in the Lung Density Analysis preset is equivalent to the lung region in Lung Analysis preset.

Summary of Non-Clinical Tests:
The Vitrea CT Lung Density Analysis software was designed, developed, and tested according to written procedures that included risk management. Software testing was completed to ensure the new features operate according to defined requirements.
The following design control measures were applied to the development of the Vitrea CT Lung Density Analysis software:

- Risk Management
- Requirements Reviews
- Code Designs
- Code Development Testing
- Code Reviews
- Design Reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included phantom testing and simulated usability testing by experienced professionals.

Risk Management:
Each risk pertaining to these features have been individually assessed to determine if the benefits outweigh the risk. Every risk has been reduced as low as possible and has been evaluated to have a probability of occurrence of harm of "Improbable." All risks for this feature were collectively reviewed to determine if the benefits outweigh the risk. Because of the risk control measures included in this feature, it is believed that the risk for the feature as a whole is extremely low. Taking into account all risks against the benefits of this feature, it has been assessed that the benefits do outweigh the risks for this feature.

During the design review, the following conclusions were reached:

- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- The overall residual risk for the project is deemed acceptable

Verification:
The software verification team's primary goal was to assure that the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As a part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Validation:
The software validation team's primary goal was assuring the software conforms to user needs and intended use. The validation team conducted workflow testing that provided evidence that the system requirements and features were implemented, reviewed and met.

Internal Validation (Phantom Testing):
The software validation team provided internal validation of Vitrea CT Lung Density Analysis software. Internal validation included internal user acceptance testing using various phantoms. Results of numerical quantities calculated by CT Lung Density Analysis were verified using CT semi-synthetic phantoms and patient based CT datasets.

External Validation:
During external validation of the CT Lung Density Analysis software, experienced users evaluated the visualization, axial plane location, quantification of density, and snapshots among other features. Each user felt that the Vitrea CT Lung Density Analysis software enables the user to assess and quantify lung density.

Summary of Clinical Tests:
The subject of this 510(k) notification, Vitrea CT Lung Density Analysis software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

Confidentiality
The Vitrea platform (K071331) relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

Integrity
The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. New DICOM produced by Vitrea is identified as such with the appropriate manufacturer tags per the DICOM standard.

Availability
The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

Accountability
The Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:
The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The Vitrea software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Substantial Equivalence Analysis Conclusion:
Vital Images believes the CT Lung Density Analysis software application has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed VIDA Pulmonary Workstation 2 software (K083227). In addition, the segmentation algorithm is similar to the algorithm available on already cleared CT Lung Analysis software (K043333).

Any noted minor differences have been explained and do not raise any different questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and performed tests demonstrate the safety and efficacy of the subject device. Based on the comparison information provided above, Vital Images believes the subject device should be found substantially equivalent to the predicate device.