



Food and Drug Administration
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Vital Images, Inc.
% Mr. Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

October 30, 2015

Re: K151283
Trade/Device Name: Lung Analysis Software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, LLZ
Dated: October 9, 2015
Received: October 13, 2015

Dear Mr. Shah:

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,

 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

Indications for Use

510(k) Number (if known)

K151283

Device Name

Lung Analysis

Indications for Use (Describe)

The separately-licensed Lung Analysis option is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary

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

Purpose of Submission: Vital Images, Inc. hereby submits this traditional 510(k) for changes that do not qualify for a Special 510(k) notification.

Submitter: Vital Images, Inc.
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Establishment Registration: 2134213

510(k) Submitter: Parthiv Shah
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510(k) Type: Traditional

Summary Date: October 9, 2015

Device Trade Name: Lung Analysis Software

Device Common Name: Radiological Image Processing Software

Device Classification Name: System, Image Processing, Radiological

Regulatory Description: Picture Archiving and Communications System

Regulation Number: 21 CFR 892.1750

Product Code: JAK

Regulatory Classification: Class II

Device Panel: Radiology

Predicate Device:

Predicate Device	Manufacturer	FDA 510(k) number
Lung Analysis (Legally Marketed Device)	Vital Images, Inc.	K043333

Reference Device:

Reference Device	Manufacturer	FDA 510(k) number
LungCARE CT (Legally Marketed Device)	Siemens Medical Solutions, Inc.	K033374

Device Description:

Lung Analysis aids in measuring and characterizing lung nodules. The interface and automated tools help to efficiently determine growth patterns and compose comparative reviews. Lung Analysis is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed. The Lung Analysis Software requires the user to identify a nodule and to determine whether it is a GGO or solid nodule in order to use the appropriate characterization tool.

Key features:

General Viewing:

- Automated segmentation of lung and airways
- Single click lung nodule segmentation tools to include solid nodules and ground glass opacity (GGO) nodules
- Restore previously segmented nodules from prior studies for comparison
- Evaluation of nodules with quantitative measurements
- Dictation Table with Lung-RADS, Fleischner Criteria and option to export to Clipboard
- Structured reporting available for export in the Viewer tab as well as the Reporting tab
- Load three studies concurrently for temporal measurements
- Select a nodule in a single time point and the tool will automatically find the nodule in the other studies loaded
- Automatic nodule tracking of all measurements
- Improved nodule management and numbering
- Ability to export snapshots, CSV and copy to Clipboard features
 - Available in Viewer and Report page

General Image Display, Manipulation, and Analysis Tools:

- Automatic software calculation of the following measurements for each segmented nodule:
 - Volume (mm³)
 - Mean diameter (mm)

- Maximum diameter (mm) (RECIST)
- Short axis diameter (mm) (WHO)
- Average/minimum/maximum densities (HU)
- Manual edit of the nodule segmentation contour lines with automatic recalculation of all measurements post-editing
- Manual specification of the following characteristics for each nodule:
 - Lobe Location
 - Shape
 - Border
- Comparison feature that allows establishing correspondence between nodules in two or three studies, and automatic calculation of the following temporal measurements between each follow-up scan and the previous scan:
 - Elapsed time in days
 - Doubling time in days
 - Percent (%) growth in nodule volume

Intended Use / Indications for Use:

The separately-licensed Lung Analysis option is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

Changes from the last 510(k) clearance K043333:

No.	Change(s)	Rationale for Changes
1	<p><u>Change-1: Support of Ground Glass Opacity (GGO) Nodule</u></p> <p>Provides the ability to probe and segment a GGO type lung nodule. In addition, this feature includes the ability to use 2nd Maximum Diameter to measure the solid portion of a GGO nodule and enabling solid nodules to be segmented prior to GGO nodules.</p>	<p>Extend the capabilities and functionality of the previously cleared Lung Analysis software to provide physicians the ability to examine and report on GGO nodules which can be cancerous.</p>
2	<p><u>Change-2: Lung Analysis Performance Enhancements</u></p> <p>Improvements to enhance the overall performance of Lung Analysis.</p>	<p>Enhance performance to include improved execution and workflow for better user experience and function.</p>
3	<p><u>Change-3: Nodule Numbering Enhancement</u></p> <p>Updated nodule numbering to automatically update numbering to the next sequential number, specifically after deletion of a previously numbered nodule.</p>	<p>Provide continuous numbering during probing and matching of nodules for better user experience.</p>

No.	Change(s)	Rationale for Changes
4	<p><u>Change-4: Dictation Table Addition</u> Added a dictation table with the ability to enable L-Rad and Fleischner criteria.</p>	Add the functionality of dictation table with L-RAD and Fleischner criteria as these are standard criteria for reporting on lung cancer screenings and diagnosis.
5	<p><u>Change-5: Replaced Current Editing Feature</u> The previous editing configuration was replaced with a Lung Region editing functionality.</p>	Replaced with Region editing to increase the lung field which is to be examined for more precise nodule segmentation.
6	<p><u>Change-6: Replaced Effective Diameter Measurement Function</u> The previous measurement function “effective diameter” was replaced with “mean diameter.”</p>	Replaced for enhanced performance and usability as mean diameter provides a more accurate measurement.

Intended for Disease / Condition / Patient Population:

The software provides Radiologists, Technologist and Oncologist, with a robust application to locate, identify, segment, measure and create reports on solid and GGO nodules. This application allows for the preparation of nodule comparison studies.

Substantial Equivalence Comparison:

- **Regulatory Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
Device Type / Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Common Name	Radiological Image Processing Software	Radiological Image Processing Software	Same
Regulation / Classification Number	21 CFR 892.2050	21 CFR 892.1750	Similar
Product Code	LLZ	JAK	Similar
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same

• **Intended Use Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
Indications for Use	The separately-licensed Lung Analysis option is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.	The separately-licensed Lung Analysis option is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.	Same

• **Technology Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
Image Communication Standard: DICOM	Yes	Yes	Same
2D Image Review	Yes	Yes	Same
3D Image Review	Yes	Yes	Same

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
2D and 3D Comparative Review	Yes	Yes	Same
3D Lung map	Yes	Yes	Same
2D Measurements	Line and ROI tools with statistics Area	Line and ROI tools with statistics Area	Same
Density Measurements	Minimum, Maximum and Average HU	Minimum, Maximum and Average HU	Same
Temporal Measurements	Elapsed Time % Growth in Volume Doubling Time	Elapsed Time % Growth in Volume Doubling Time	Same
Workflow	Point-and-click detection Automated contouring Automated measurements Manual correction	Point-and-click detection Automated contouring Automated measurements Manual correction	Same
Multi-planar reformatting	MPR in any user-defined linear plane, MIP and average	MPR in any user-defined linear plane, MIP and average	Same
Auto-cine	Yes	Yes	Same
Save workflow	Restorable state from user snapshots	Restorable state from user snapshots	Same
Reporting	Detailed tabular report with auto-population of user-defined key images	Detailed tabular report with auto-population of user-defined key images	Same
Printing	Printing to standard windows printers	Printing to standard windows printers	Same

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
Ease of Use	Visualization presets and semi-automated steps for typical image review procedures	Visualization presets and semi-automated steps for typical image review procedures	Same

• **Technology Comparison with the Reference Device**

Criteria	Reference Device	Subject Device	Comparison
	LungCARE CT (K033374)	Lung Analysis (Modified Lung Analysis Software)	
<p>Feature: Support of GGO lung nodule</p> <p>The GGO lung nodule feature allows for detection, segmentation and tracking over time of GGO nodules.</p>	Yes	Yes	<p>Same</p> <p>Note: The added GGO lung nodule feature is similar to the feature on the already cleared Siemens Medical Solutions, Inc., LungCARE CT (“Reference Device”) software package by K033374. Therefore, the added feature does not raise new questions of safety and effectiveness.</p>

- Differences in Technology with the Predicate Device

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
<p>Feature: <u>Support of Ground Glass Opacity (GGO) Nodule and 2nd Maximum Diameter Rulers</u></p> <p>Provides the ability to probe and segment a GGO type lung nodule. In addition, this feature includes the ability to use 2nd Maximum Diameter to measure the solid portion of a GGO nodule and enabling solid nodules to be segmented prior to GGO nodules.</p>	No	Yes	<p>The added features do not affect the intended use or fundamental scientific technology of the already cleared Lung Analysis software (K043333).</p> <p>Note: The added GGO lung nodule feature is similar to the feature on the already cleared Siemens Medical Solutions, Inc., LungCARE CT (“Reference Device”) software package by K033374. Therefore, the added feature does not raise new questions of safety and effectiveness.</p>
<p>Enhancement: Lung Analysis Performance</p> <p>Improvements to enhance the overall performance of Lung Analysis.</p>	No	Yes	<p>The added performance enhancements do not affect the intended use or fundamental scientific technology of the already cleared Lung Analysis software (K043333).</p>

Criteria	Predicate Device	Subject Device	Comparison
	Lung Analysis (K043333)	Lung Analysis (Modified Lung Analysis Software)	
<p>Enhancement: Nodule Numbering</p> <p>Updated nodule numbering to automatically update numbering to the next sequential number, specifically after deletion of a previously numbered nodule.</p>	No	Yes	This enhancement does not affect the intended use or fundamental scientific technology of the already cleared Lung Analysis software (K043333).
<p>Enhancement: Dictation Table</p> <p>Added a dictation table with the ability to enable L-Rad and Fleischner criteria.</p>	No	Yes	This enhancement does not affect the intended use or fundamental scientific technology of the already cleared Lung Analysis software (K043333).
<p>Change: Replaced Current Editing Feature</p> <p>The previous editing configuration was replaced with a Lung Region editing functionality.</p>	No	Yes	This change does not affect the intended use or fundamental scientific technology of the already cleared Lung Analysis software (K043333).
<p>Change: Replaced Effective Diameter Measurement Function</p> <p>The previous measurement function "effective diameter" was replaced with "mean diameter."</p>	No	Yes	This change does not affect the intended use or fundamental scientific technology of the already cleared Lung Analysis software (K043333).

- **Substantial Equivalence Analysis**

The enhancements in the software do not affect the intended use or alter the fundamental scientific technology of the legally marketed Lung Analysis software (K043333). The modified Lung Analysis software has the same indications for use, principle of operation, and performs the same technological functions as the already cleared Lung Analysis software - K043333 (Predicate Device). The added GGO lung nodule feature is similar to the already cleared Siemens Medical Solutions, Inc., LungCARE CT (K033374) (Reference Device). The modifications are not consequential from the standpoint of device operation, safety, effectiveness or intended use. Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device.

Summary of Non-Clinical Tests:

The changes to the software were designed, developed and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new features operate according to their requirements.

Testing included verification, validation, and evaluation on previously acquired medical images. The following quality assurance measures were applied to the development:

- Risk Management
- Requirements reviews
- Code designs
- Code reviews
- Design reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included simulated usability testing by independent experienced medical professionals.

Risk Management:

Each risk pertaining to this feature has 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 at least "Remote". All risks for this feature were collectively reviewed to determine if the benefits outweigh the risk. Based on the post market information contained in our Clinical Evaluation Report, injury or death is very rare for our product and products similar to ours. Because of this history and 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:

- All risks were reduced as low as possible
- 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.

Phantom Testing:

The phantom tests were performed is to verify that the Lung Analysis application generates reliable volumes and related linear and CT attenuation measurements of pulmonary ground glass opacifications (GGOs). The validation of the GGO measurements is based on anthropomorphic lung phantoms with synthetic nodules. Moreover, accuracy, intra-reader variability and inter-reader variability are assessed using patient-based datasets. In summary the following tests were performed:

1. **GGO volume accuracy and precision:** the accuracy and the precision of the GGO volume measurements after semi-automatic segmentation and before manual editing are within acceptable.
2. **GGO volume reproducibility:** the intra-reader and inter-reader agreement for the GGO volume measurements (patient-based dataset - after manual editing) are within acceptable ranges.
3. **GGO diameters accuracy and precision:** the accuracy and the precision of the GGO longest nodule diameter measurements after semi-automatic segmentation and before manual editing are within acceptable ranges.
4. **GGO mean CT attenuation accuracy and precision:** the accuracy and the precision of the GGO mean CT attenuation (HU) measurements after semi-automatic segmentation and before manual editing are within acceptable ranges.

The following table summarize the performed phantom tests:

ID	Test Case Name	Parameters	Type	Status
Test 1.a	Evaluate the accuracy and precision of the GGO volume measurement for Siemens 64-CT scanner.	GGO volume Bias: Absolute error (mm3) Absolute percentage normalized error %(APNE) Precision: Percent Repeatability Coefficient (PRC)	Phantom dataset	Passed

ID	Test Case Name	Parameters	Type	Status
Test 1.b	Evaluate the accuracy and precision of the GGO volume measurement for Philips 16-CT scanner.	GGO volume Bias: Absolute error (mm ³) Absolute percentage normalized error %(APNE) Precision: Percent Repeatability Coefficient (PRC)	Phantom dataset	Passed
Test 1.c	Evaluate the accuracy and precision of the GGO volume measurement for Toshiba AQ1 320-CT scanner	GGO volume Bias: Absolute error (mm ³) Absolute percentage normalized error %(APNE) Precision: Percent Repeatability Coefficient (PRC)	Phantom dataset	Passed
Test 2	Evaluate the intra-reader and inter-reader variability of GGO volume measurements on patient-based datasets.	<u>Intra-reader agreement and Inter-reader agreement:</u> Concordance Correlation Coefficient (CCC _{inter} , Total Deviation Index (TDI), Coverage Probability (CV)	Patient-based dataset User-edited GGOs	Passed
Test 3	Evaluate the accuracy and precision of the GGO longest diameter measurement for Toshiba AQ1 320-CT scanner.	Longest diameter (mm) Bias: Absolute error (mm) Absolute percentage normalized error %(APNE) Precision: within-nodule standard deviation (wSD).	Phantom dataset	Passed
Test 4	Evaluate the accuracy and precision of the GGO mean attenuation measurement for Toshiba AQ-One CT scanner.	Mean attenuation (HU) Bias: Absolute error (HU) Absolute percentage normalized error %(APNE) Precision: within-nodule standard deviation (wSD).	Phantom dataset	Passed

Measurement Accuracy:

The following table summarize accuracy i.e. average bias (APE %) and precision (PRC %) for lung GGO volume measurement performed on Toshiba scanner with 100mAs exposure.

GGO Ref. diameter	Bias APE%	Precision PRC%
5mm	15.04%	24.74%
8mm	16.15%	11.85%
10mm	5.49%	3.24%
12mm	2.98%	3.38%

The accuracy and precision results of the GGO volume measurements may vary for other CT scanner types or CT manufacturers and for other acquisition conditions involving tube current, slice thickness, reconstruction filters, etc.

External Validation:

During external validation of Lung Analysis software, experienced medical professionals evaluated the application. All validators confirmed that the Lung Analysis software fulfills its intended uses.

Summary of Clinical Tests:

The subject of this traditional 510(k) notification, Lung Analysis software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- **Confidentiality**
The Vitrea platform (K150258) 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.
- **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 tracks authenticated and authorized user operations along with information on what data was 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 Lung Analysis 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

Conclusion:

Vital Images believes that the Lung Analysis software application has the same intended use and indications and similar principle of operation, and technological characteristics as the predicate and reference devices. Any minor differences noted have been explained and do not raise any new 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 device in comparison to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device. The Lung Analysis software device is as safe and effective as the predicate device.