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

September 17, 2014

Imbio LLC
% Mr. Jason Sheard
Director of Operations
227 Colfax Avenue N., Suite 144
MINNEAPOLIS MN 55405

Re: K141069
Trade/Device Name: Imbio 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: April 14, 2014
Received: August 19, 2014

Dear Mr. Sheard:

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

Janine M. Morris
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)*
K141069

Device Name
Imbio CT Lung Density Analysis Software

Indications for Use *(Describe)*
The Imbio CT Lung Density Analysis Software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis and follow up examinations. The Imbio CT Lung Density Analysis Software 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 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)

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)*

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

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5 510(k) Summary

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Submitter:	Imbio LLC 227 Colfax Ave N, Suite 144 Minneapolis MN 55405 USA
Contact Person:	Jason Sheard Director of Operations Telephone: 612-520-7360 Email: jasonsheard@imbio.com Imbio LLC 227 Colfax Ave N, Suite 144 Minneapolis MN 55405 USA
Date Prepared:	August 14, 2014
Trade Name:	Imbio CT Lung Density Analysis Software
Common/Usual Name:	Software Accessory to a Computed Tomography Device
Classification:	21 CFR 892.1750 Product Code 90 JAK, Class II Computed tomography x-ray system
Product Code:	90 JAK, Class II
Manufacturer:	Imbio LLC 227 Colfax Ave N, Suite 144 Minneapolis MN 55405 USA
Establishment Registration:	**N/A**
Predicate Device:	**Manufacturer:** VIDA Diagnostics **Trade name:** VIDA Pulmonary Workstation 2 (PW2) **510(k) Number:** K083227 **Date Cleared:** November 18, 2008

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Device Description	The Imbio CT Lung Density Analysis Software (Imbio LDA) is a set of image post-processing algorithms that perform image segmentation, registration, thresholding, and classification on CT images of human lungs. The algorithms within the Imbio CT Lung Density Analysis Software are combined into a single command-line executable program that may be run directly from the command-line or through scripting. The Imbio CT Lung Density Analysis Software program performs segmentation, then registration, then thresholding and classification. The program reads in DICOM datasets, processes the data, then writes output DICOM files to a specified directory. The Imbio CT Lung Density Analysis Software is a command-line software application that analyzes DICOM CT lung image datasets and generates reports and DICOM output that show the lungs segmented and overlaid with color-codings representing the results of its thresholding and classification rules. It has simple file management functions for input and output, and separate modules that implement the CT image-processing algorithms. Imbio CT Lung Density Analysis Software does not interface directly with any CT or data collection equipment; instead the software imports data files previously generated by such equipment.
Intended Use	The Imbio CT Lung Density Analysis Software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis and follow up examinations. The Imbio CT Lung Density Analysis Software 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, and reporting tools are provided.

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Summary of Technical Comparisons	**Similarities:** Both the predicate device and the Imbio CT Lung Density Analysis Software are software applications that import CT DICOM data files, analyze them, and produce reports with quantitative and graphical results. The functionality of Imbio CT Lung Density Analysis Software is substantially equivalent to the predicate device. Direct quantitative comparisons using the same CT lung scans yielded similar results. **Differences:** The Imbio Lung Density Analysis Software provides a command-line interface, while the predicate device provides a graphic user interface. The Imbio Lung Density Analysis Software provides automated registration of the Inspiration / Expiration image pairs, while this registration is manual (i.e., visually performed by the radiologist) with the predicate device. The predicate device provides an interactive visualization of the reconstructed three-dimensional volume, low-density cluster analysis, and an airway report. These features are not part of the Imbio CT Lung Density Analysis Software. These differences do not affect the efficacy and safety of the Imbio CT Lung Density Analysis Software.
Non-Clinical Testing	The following testing was conducted on Imbio CT Lung Density Analysis Software by analyzing CT datasets available upon request from the COPDGene study (www.copdgene.org) and the DIR-Lab (www.dir-lab.com): • Direct predicate comparison for scan processing completion, segmentation, and thresholding. This was done to verify that the software functions according to its specifications and to support substantial equivalence. • Software verification and validation testing for each requirement specification. • Software verification and validation testing for each algorithmic function. • Software verification and validation testing at the unit, integration, and system level The following quality assurance measures were applied during software development: • Software Development Life Cycle • Software Risk Assessment. • Risk Assessment of Off-the-Shelf (OTS) Software. • Software Configuration Management and Version Control. • Software issue tracking and resolution.

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Design Validation	Design validation was performed using the Imbio CT Lung Density Analysis Software in actual and simulated use settings. The results support substantial equivalence to the predicate device and demonstrate that the Imbio CT Lung Density Analysis Software is safe for its intended use.
Clinical Testing	This technology is not new, therefore a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.
Conclusion:	We conclude that the results of testing show the Imbio CT Lung Density Analysis Software to be substantially equivalent to the predicate device. The Imbio CT Lung Density Analysis Software has the same technological characteristics as the predicate device in that it has a similar intended use, same general operating principle, and same technology. The specific details of the predicate device may vary from those of Imbio CT Lung Density Analysis Software, but testing shows that similar results are produced. It has been shown in this 510(k) submission that the differences between the Imbio CT Lung Density Analysis Software and the VIDA PW2 (K0832277) do not raise any questions regarding safety and effectiveness. The Imbio CT Lung Density Analysis Software, as designed and manufactured, is substantially equivalent to, and as safe and effective as, the referenced predicate device.