VIDA Diagnostics Inc.
℅ Alex Morris
Director, Quality and Regulatory
2500 Crosspark Road, W250 BioVentures Center
CORALVILLE IA 52241

August 7, 2020

Re: K200990
Trade/Device Name: VIDA|vision
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 19, 2020
Received: May 20, 2020

Dear Alex Morris:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200990

Device Name
VIDA|vision

Indications for Use *(Describe)*
The VIDA|vision software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis and follow up examinations. VIDA|vision 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 combined with a dedicated workflow. The VIDA|vision 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.

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

K200990

Submitter:	VIDA Diagnostics, Inc. 500 Crosspark Rd. W250 BioVentures Center Coralville, IA 52241 USA
Date Prepared:	July 25, 2020
Contact Person:	Alex Morris, Director, Quality and Regulatory VIDA Diagnostics, Inc. 2500 Crosspark Rd. W250 BioVentures Center Coralville, IA 52241 USA Cell Phone: (647) 470.4363 Office Phone: (855) 900.8432 Email: amorris@vidalung.ai
Submission Date:	May 19, 2020
Trade Name:	VIDA|vision
Regulation Description:	Computed tomography x-ray system
Common Name:	Medical Imaging Software for Computed Tomography Devices
Regulation:	21 CFR 892.1750
Product Code:	JAK
Regulatory Class:	Class II
Predicate Device:	Pulmonary Workstation 2 (PW2) by VIDA Diagnostics Inc. Regulation: 21 CFR 892.1750 Product Code: JAK Regulatory Class: Class II Regulation Description: Computed tomography x-ray system Submission Number: K083227

Description of Device:

VIDA|vision is a self-contained image analysis software package. This real-time interactive evaluation in space and time of CT volume datasets provides the reconstruction of two-dimensional images into a three-dimensional image format.

VIDA|vision can be used to support the physician in the diagnosis, treatment planning, and documentation of chest diseases, including lung cancer, asthma, COPD, interstitial lung disease and other lung abnormalities e.g. when examining the pulmonary and thoracic tissue (i.e. lung parenchyma) in CT thoracic datasets.

Evaluation (3D segmentation & isolation of sub-compartments, volumetric analysis, density evaluations, and low density cluster analysis), editing, and reporting tools are combined with a dedicated workflow.

VIDA|vision 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.

VIDA|vision provides computed tomography (CT) viewing, airway analysis, and parenchymal density analysis in one application. VIDA|vision provides imaging of bronchial airways that can be used to assess therapy effectiveness and treatment plan based on CT scan data. VIDA|vision reconstructs multiple cross-section images from CT data into a computer model displaying complex bronchial branches.

VIDA|vision provides quantitative measurements and tabulates quantitative properties. VIDA|vision 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 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.

VIDA|vision has functions for loading, analyzing, and saving datasets, and will generate screen displays, computations and aggregate statistics. VIDA|vision data output may be exported in pdf format or to a csv file.

Indications for Use Statement:

The VIDA|vision software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis and follow up examinations. VIDA|vision 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 combined with a dedicated workflow. The VIDA|vision 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.

Comparison to Predicate:

The focus of this submission is to introduce deep learning-based segmentation algorithms to the proposed software to automatically segment lung regions.

Table 1 - Comparison of Characteristics

Manufacturer	510(k) Submitter	Predicate	Differences
	VIDA Diagnostics, Inc.	VIDA Diagnostics, Inc.	
Trade Name	VIDA|vision (formerly VIDA Pulmonary Workstation 2 (PW2))	VIDA Pulmonary Workstation 2 (PW2)	
510(k) Number	K200990	K083227	
Product Code	JAK	JAK	n/a
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	n/a
Regulation Name	System, X-Ray, Tomography, Computed	System, X-Ray, Tomography, Computed	n/a
Intended Use/Indications for Use	The VIDA|vision software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis and follow up examinations. VIDA|vision can be used to	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	n/a

	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 combined with a dedicated workflow. The VIDA|vision 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.	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 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.	
Image Source Modalities	CT	CT	n/a
DICOM Conformance	Yes	Yes	n/a
Comparative Review	2D, 3D	2D, 3D	n/a
3D Lung mapping	yes	yes	n/a
3D measurements	Volume Effective Diameter	Volume Effective Diameter	n/a
2D	Line and ROI tools with	Line and ROI tools with	n/a

measurements	statistics Diameter 2D Area	statistics Diameter 2D Area	
Density measurements	Minimum, maximum and average HU	Minimum, maximum and average HU	n/a
Deployment	Standalone computer/ distributed	Standalone computer	Subject device offers distributed configuration in addition to standalone, unlike the predicate device
OS	Windows	Linux	transitioned from Linux to Windows.
User Interface	yes - w/ limited modifications	yes	limited modifications to improve the user experience and accommodate new functionality and a newer operating system.
Algorithm	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	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,	Unlike the predicate device, the subject device provides deep learning-derived segmentation.

	distinction is common in the industry. A non-adaptive deep learning-based algorithm is applied to the CT imaging data to automatically segment lung regions.	such distinction is common in the industry.	
Workflow	Automated contouring Automated measurements Manual Correction <u>Distinct user workflows:</u> Airway Mapping and Lung Volume Analysis	Automated contouring Automated measurements Manual Correction	Subject device offers functionality to support distinct user workflows, unlike predicate.
Graphic User Interface	Yes	Yes	n/a
Interactive 3D Visualization	Yes	Yes	n/a
Input/Output	Users can browse, select, and load CT scan files. Users can save and load analyses, export via reporting tools. CT scan files can be organized by user-defined projects, and tracked by usage. User can generate a report that displays quantitative data items that can be saved. DICOM info displayed. Data import through DICOM query/ retrieve available.	Users can browse, select, and load CT scan files. Users can save and load analyses, export via reporting tools. CT scan files can be organized by user-defined projects, and tracked by usage. User can generate a report that displays quantitative data items that can be saved. DICOM info displayed.	Unlike the predicate device, the subject device supports DICOM query/retrieve data importation.
Path Planning	yes - airways and lung tissue	yes - airways only	Like the

			predicate, the subject device provides path planning to airway segments. Unlike the predicate, the subject device includes path planning to a region of interest in the lung tissue.
User editing	yes	yes	n/a
Reports	yes - csv and pdf format configurable for specific use cases	yes - csv only	Unlike the predicate, the subject device offers pre-existing metrics and visualizations packaged for specific use cases
Scan quality assessment	• Scan protocol is assessed for compatibility with software • incompatibility issues flagged during import and on report • Scanner calibration assessment • Warning issued for out-of-range air/blood measurements	• Scan protocol is assessed for PW2 compatibility • incompatibility issues flagged during import and on report • Scanner calibration assessment • Warning issued for out-of-range air/blood measurements	n/a

Clinical Testing:

No human clinical testing was required to support a substantial equivalence finding.

Non-clinical testing:

The device labeling contains instructions for use and any necessary precautions and warnings to support the safe and effective use of the device. Known hazards were identified and mitigated in accordance with the ISO 14971 standard. Verification and validation activities were performed in accordance with FDA QSR and the IEC 62304 standard. Testing consisted of unit, regression, performance, and integrated system testing. Lung and lobe segmentation performance was tested against the predicate performance to demonstrate substantial equivalence. Results of testing demonstrate that the device has met all product specifications and user needs when used within its intended use.

Consensus Standards:

- ISO 14971:2007 Medical devices -- Application of risk management to medical devices.
- IEC 62304:2006Amd2015 Medical device software -- Software lifecycle processes.
- NEMA PS 3.1--3.20 (2016) Digital Imaging and Communication in Medicine (DICOM) Set
- ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels,
- labelling and information to be supplied -- Part 1: General requirements.

Statement of Substantial Equivalence:

The subject device, VIDA|vision, is substantially equivalent to the predicate device. Differences do not raise new issues about the safety and effectiveness of the software.