K083227

NOV 18 2008

5 510(k) Summary 510(k) Summary of Safety and Effectiveness [As required by 21 CFR 807.92(c)]

General information regarding the VIDA Diagnostics, Inc., Inc. VIDA Pulmonary Workstation 2 *(PW2)* is contained in the following table 1.

Table 1: General Information

Manufacturer	VIDA Diagnostics 100 Oakdale Campus, Suite 225 TIC Iowa City, IA 52242 USA FDA Establishment Registration No. *Pending*
Submitter's Name, Title and Phone Contact	Jack Slovick, RA/QA, 763-639-0238 (phone) RA/QA Affairs Fax: 763-434-0966 **VIDA Diagnostics** 100 Oakdale Campus, Suite 225 Technology Innovation Center Iowa City, IA 52242
Trade Name	VIDA Pulmonary Workstation 2 *(PW2)*
Common Name	Computed tomography x-ray system
Classification	This device has been classified by the Reproductive, Abdominal and Radiological Panel into Class II (21 CFR 892.1750), Product Code 90 JAK Class II
Date Prepared	October 13, 2008
Intended Use	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 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.
Identification of Equivalent Devices	Manufacturer: Siemens Medical Solutions Trade name: InSpace 4D – Software Package with Extended Functionality 510(k) Number: K071513 Date Cleared: June 26, 2007
Compliance with Special Controls or Performance Standards	Special Controls: No special controls or mandatory performance standards for this device have been established. Voluntary standards were used throughout the development; testing and manufacturing processes (see section 9.0 for detailed list of voluntary standards that were used)
Product Code	90 JAK, Class II
Regulation Number	21 CFR 892.1750
Reason for Premarket Notification	VIDA Diagnostics, Inc. intends to introduce the VIDA Pulmonary Workstation *2 (PW2)* into interstate commerce for commercial distribution.

1 General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, VIDA Diagnostics adheres to recognized and established industry practice and standards.

2 Substantial Equivalence

The VIDA Pulmonary Workstation *2 (PW2)*, addressed in this pre-market notification, is substantially equivalent to the following commercially available software package.

3 Manufacturer Product 510(k) Clearance date

Siemens *InSpace 4D* K071513 June 26, 2007

In summary, VIDA Diagnostics is of the opinion that VIDA Pulmonary Workstation *2 (PW2)* does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

3. Intended Use

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 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.

4. Device Description

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. Figure 1 shows the basic Input/ Output of the CT volume converting to a digitized, colorized picture.

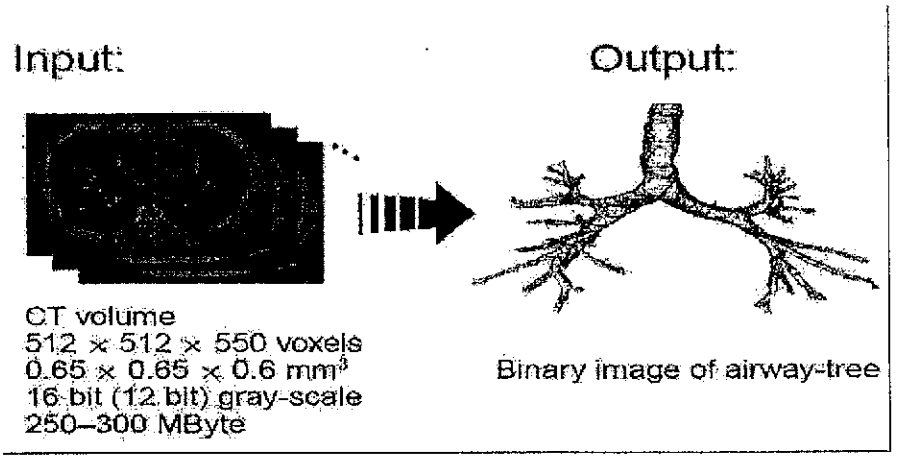

Figure 1: Input/ Output

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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2008

VIDA Diagnostics, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K083227
Trade/Device Name: VIDA Pulmonary Workstation 2 (PW2)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 31, 2008
Received: November 3, 2008

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083227

VIDA Diagnostics

4 Indications for Use Statement

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 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.

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083227

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____
(per 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)