K130552
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510(k) Summary
CT Pulmonary Analysis
Qi Imaging, LLC

JAN 13 2014

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

General Information

Trade Name	CT PULMONARY ANALYSIS
Common Name	Picture Archiving and Communications System (PACS)
Classification Name	System, Image Processing, Radiological (21 CFR § 892.2050 - LLZ)
Applicant:	**Qi Imaging, LLC** 1235 Radio Road, Suite 110 Redwood City, CA 94065 Tel 650-413-1300 Fax 650-596-7319
Contact	Richard Ball Director, Regulatory and Quality Affairs

Intended Use

Ziostation is an image processing workstation software package designed to run on standard PC hardware. It provides for the viewing, quantification, manipulation, communication, printing, and management of medical images. It is intended for use by trained medical professionals to aid in their reading and review of such data. In addition, Ziostation has the following indications:

The **CT PULMONARY ANALYSIS** software option is an independent image analysis software tool providing additional image process capabilities to the Ziostation system. The CT PULMONARY ANALYSIS option is intended to assist the physician in assessing possible airway obstruction.

Predicate Devices

Table 2: Predicate devices to CT Pulmonary Analysis Software Tool

Qi Imaging tool	Manufacturer of Predicate Device	Device Name	510(k) Number
CT PULMONARY ANALYSIS	VIDA	VIDA Pulmonary Workstation 2.0	K083227
	Intrasense	Myrian v1.11.2 XP-Lung	K113620

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Device Description

CT PULMONARY ANALYSIS is an optional software package designed to be used with the basic Ziostation DICOM image management system to further aid clinicians in their analysis of anatomy, physiology and pathology. Universal functions such as data retrieval, storage, management, querying and listing, and output are handled by the basic Ziostation software. The added capabilities provided by this additional software option for use with CT DICOM compliant images are:

- Segmentation of lung and bronchial airway
- Contour detection of airway walls
- Evaluation of bronchial dimensions
- Observation of cross-sectional image and variance of diameter/thickness/area of airway wall along airway
- Integrated 3D visualization with MPR or A/C/S slice/slab viewing
- Low Attenuation Analysis by Lung Sections

Materials

This software tool consists entirely of software. No materials are contained in this product.

Testing Summary

The CT PULMONARY ANALYSIS software package successfully completed integration testing/verification testing prior to Beta validation. Software Beta testing/validation was successfully completed prior to final testing and release. In addition, potential hazards have been addressed by the Qi Imaging Risk Management process.

Summary of Substantial Equivalence

CT PULMONARY ANALYSIS is substantially equivalent in intended use and function to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2014

Qi Imaging, LLC
% Mr. Richard Ball
Director, Regulatory & Quality Affairs
1235 Radio Road, Suite 110
REDWOOD CITY CA 94065

Re: K130552
Trade/Device Name: CT Pulmonary Analysis
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 7, 2014
Received: January 8, 2014

Dear Mr. Ball:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 on last page.

510(k) Number *(if known)*
K130552

Device Name
CT PULMONARY ANALYSIS Software Tool for Ziostation

Indications for Use *(Describe)*

Ziostation is an image processing workstation software package designed to run on standard PC hardware. It provides for the viewing, quantification, manipulation, communication, printing, and management of medical images. It is intended for use by trained medical professionals to aid in their reading and review of such data. In addition, Ziostation has the following indication:
The CT PULMONARY ANALYSIS software option is an independent image analysis software tool providing additional image process capabilities to the Ziostation system. The CT PULMONARY ANALYSIS option is intended to assist the physician in assessing possible airway obstruction.

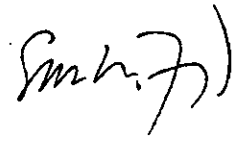
Type of Use *(Select one or both, as applicable)*

☒ 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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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."