



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Qi Imaging, LLC
% Mr. Richard Ball
Director, Regulatory & Quality Affairs
1301 Shoreway Road, Suite 325
BELMONT CA 94002

November 4, 2015

Re: K151212
Trade/Device Name: Ziostation2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 8, 2015
Received: October 14, 2015

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 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a prominent "R" and "O".

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)
K151212

Device Name
Ziostation2

Indications for Use (Describe)

Ziostation2 is an image processing application software available for installation onto customer owned hardware. This application software can be networked to provide for sharing of resources.

This application software receives medical images from modalities (medical image scanning devices such as CT) or image archives such as PACS through network or media and provides for the viewing, quantification, manipulation, communication, printing, and management of medical images.

This application software is intended for use by trained medical professionals to supplement generally accepted methods of interpreting radiological images.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor whose characteristics are approved by the regulatory agency governing the market within which Ziostation2 is being offered.

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.

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510(k) Summary
Ziostation2
Qi Imaging, LLC

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

General Information

Trade Name	Ziostation2
Common Name	Picture Archiving and Communications System (PACS)
Classification Name	System, Image Processing, Radiological (21 CFR § 892.2050 – LLZ)
Applicant:	Qi Imaging, LLC 1301 Shoreway Road, Suite 325 Belmont, CA 94002 Tel 650-413-1364 Fax 650-596-7319
Contact	Richard Ball Sr. Director, Regulatory and Quality Affairs

Intended Use

- Ziostation (hereinafter “this application software”) is an image processing application software available for installation onto customer-owned hardware. This application software can be networked to provide for sharing of resources.
- This application software receives medical images from modalities (medical image scanning devices such as CT) or image archives such as PACS through network or media and provides for the viewing, quantification, manipulation, communication, printing, and management of medical images.
- This application software is intended for use by trained medical professionals to supplement generally accepted methods of interpreting radiological images.
- Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor whose characteristics are approved by the regulatory agency governing the market within which Ziostation2 is being offered.

Note: The clinician retains the ultimate responsibility for making the proper diagnosis based on standard radiological practices and visual comparison of the separate, unprocessed images. Ziostation2 is a tool to be used in support of those standard practices and visual comparisons.

Predicate Devices

Predicate devices to Ziostation2 Software Tool

Device Name	510(k) Number
Ziostation (Multiple Protocol Enhancements)	K070205
Ziostation with Cardiac Function Analysis and Calcium Scoring Software	K083446
CARDIQ Express v2.0	K073138
EBW NM 2.0	K111336
PET VCAR	K063324
CT Perfusion 4	K052839
Vitrea CT Myocardial Analysis	K112531
Syngo Volume Perfusion, CT Body	K092013
AW Volume Share 5	K110834
Synapse 3D Liver Analysis	K110186
Signa HDxT HD	K121676
Achieva R2 1.5T/3.0T	K110151
^{Sure} Subtraction Ortho CSSO-001A	K130960
CardEP	K031261
Vitrea CT Transcatheter Aortic Valve Replacement Planning	K122578

Device Description

ZIOSTATION2 is a basic 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 Ziostation2 software. Various imaging tools and techniques can be invoked to process images from the following image types: CT, MRI, Ultrasound, Digital X-ray X-ray Angiography, PET, SPECT, NM, SC, Mammography, X-ray Radiofluoroscopic image, RT Image.

New Features – Substantial Equivalence Discussion

Image Viewing/Tool Enhancements – Ref. Ziostation K070205 and Ziostation w/ Cardiac Function Analysis K083446 as predicate devices

Capability	Substantial Equivalence
Fusion Viewer	K070205 Fusion Viewer is a workflow enhancement and is substantially equivalent to the current Ziostation ability to fuse images.
PhyZiodynamics	K070205 PhyZiodynamics reconstructs data with the addition of noise reduction and motion coherence to improve image quality and is substantially equivalent to the current Ziostation data reconstruction capability.

CT Coronary Analysis	K070205 (Secondary K073138) Improvements to CT Coronary include automatic vessel labeling and color coding of HU ranges of specified areas for easier visualization of suspected areas of interest. This tool with its expanded capabilities is substantially equivalent to the current Ziostation coronary analysis tool.
CT Colon Analysis	K070205 (Secondary K110834) The added capability to automatically measure and report on user-specified ROI's is a workflow enhancement. This capability is substantially equivalent to the current Ziostation CT Colon tool.
CT/SPECT Cardiac Fusion	K070205 (Secondary K111336) The functionality being added to the already cleared CT/SPECT Cardiac Fusion ability of the current Ziostation device is to provide data and polar maps of stress, rest, reversibility and washout. This workflow enhancement is substantially equivalent to the current Ziostation CT/SPECT Cardiac Fusion tool.
SUV Measurement	K070205 (Secondary K063324) Uses current multi-exam comparison capability of PET images to visualize and monitor disease progression or response to treatment or therapy. This workflow enhancement is substantially equivalent to the current Ziostation PET imaging tool.
CT Subtraction	K070205 (Secondary K130960) CT Subtraction improves the current capability of contrast enhancement visualization. This improvement is substantially equivalent to the current Ziostation contrast enhancement capability.
EP Planning	K070205 (Secondary K031261) Using currently available display and measurement tools, EP Planning allows the physician to concentrate on certain specific areas of the heart. This tool is substantially equivalent to the current Ziostation display and measurement capability.
TAVR	K070205 (Secondary K122578) Using currently available display and measurement tools, TAVR allows the physician to concentrate on certain specific areas of the heart, including aortic valve and surrounding structures. This tool is substantially equivalent to the current Ziostation display and measurement capability.
CT Cardiac RV	K083446 (Secondary K110834) Using currently available display and measurement tools, CT Cardiac RV adds the capability to calculate and display various functional parameters of the right ventricle. This added capability is substantially equivalent to the current Ziostation capability to provide functional ventricular information.

Additional Image Processing Functionalities

CT Perfusion Analysis	K052839 Both the Qi Imaging feature and the GE predicate feature are image analysis software applications that allow evaluation of dynamic CT data following the injection of a compact bolus of contrast material, generating information with regard to changes in image intensity over time. Both features allow assessment of the type and extent of various perfusion related parameters. The Qi Imaging CT Perfusion feature is substantially equivalent to GE CT Perfusion 4.
CT Volume Perfusion	K052839 Both the Qi Imaging feature and the GE predicate feature are image analysis software applications that allow evaluation of dynamic CT data following the injection of a compact bolus of contrast material, generating information with regard to changes in image intensity over

	time. Both features allow assessment of the type and extent of various perfusion related parameters in user-specified planes of orientation. The Qi Imaging CT Volume Perfusion feature is substantially equivalent to GE CT Perfusion 4.
CT Myocardial Perfusion	K112531 Both the Qi Imaging feature and the Vital Images feature provide color-coded polar maps of the contrasted myocardium based on the calculation of transmural perfusion ratios. The Qi Imaging CT Myocardial Perfusion feature is substantially equivalent to Vital Images Vitrea CT Myocardial Analysis
CT Dynamic Myocardial Perfusion	K092013 Both the Qi Imaging feature and the Siemens feature provide 3-dimensional calculation of Blood Flow, Blood Volume and other functional parameters by displaying color coded maps of individual parameters on user-specified regions of the myocardium. The Qi Imaging CT Dynamic Myocardial Perfusion feature is substantially equivalent to Siemens syngo Volume Perfusion – CT Body
CT Lesion Analysis	K110834 Both the Qi Imaging feature and the GE feature allow extraction and measurement of lesions, enabling observation of changes over time. The Qi Imaging CT Lesion Analysis feature is substantially equivalent to GE AW Volume Share 5
CT Liver Analysis	K110186 Both the Qi Imaging CT Liver feature and the Fuji Film feature allow auto-segmentation/calculation of liver features such as liver structure, volumes, tumors and manual definition of separation plane proposals. The Qi Imaging CT Liver Analysis feature is substantially equivalent to Fuji Film Synapse 3D Liver Analysis
MR Tractography	K121676 and K110151 Qi Imaging MR Tractography feature, the GE device and the Philips device all present DTI Tractography data showing colored tracts of various anatomical fibers of interest overlaid onto the surrounding anatomy. The Qi Imaging MR Tractography feature is substantially equivalent to the comparable software features of both GE Signa HDXT and Philips Achieva R41.5T & 3.0T.

Materials

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

Testing Summary

The ZIOSTATION2 software package successfully completed integration testing/verification testing prior to Beta validation. Regression testing was also performed on all functionality present on Ziostation. 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

ZIOSTATION2 is substantially equivalent in intended use and function to the composite of predicate devices identified above.