Ziosoft, Inc.
℅ Richard Ball
Regulatory Consultant
Ziosoft USA Inc.
1301 Shoreway Road, Suite 325
BELMONT, CA 94002

Re: K181892
   Trade/Device Name: Ziostation2
   Regulation Number: 21 CFR 892.2050
   Regulation Name: Picture Archiving And Communications System
   Regulatory Class: Class II
   Product Code: LLZ, JAK, LNH
   Dated: June 29, 2018
   Received: July 13, 2018

Dear Richard 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

[Signature]

Robert A. 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

Device Name
Ziostation2

Indications for Use (Describe)
• This application is 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 image data (CT, MRI, Ultrasound, Digital X-ray, X-ray Angiography, PET, SPECT, Nuclear Medicine, Secondary Capture, Mammography, X-ray Radiofluoroscopic image, and RT Image) from modalities 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 only 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 this application 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.

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

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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
Classification Name System, Image Processing, Radiological (21 CFR § 892.2050 – LLZ)

Applicant: Ziosoft, Inc.
MitaKokusai Bldg., 1-4-28 Mita,
Minato-ku, Tokyo 108-0073, Japan

Contact Richard Ball
Regulatory Consultant
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Intended Use

• This application is 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 image data (CT, MRI, Ultrasound, Digital X-ray, X-ray Angiography, PET, SPECT, Nuclear Medicine, Secondary Capture, Mammography, X-ray Radiofluoroscopic image, and RT Image) from modalities 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 only for use by trained medical professionals to supplement generally accepted methods of interpreting radiological images.

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Predicate Devices

Predicate devices to ZioStation2 Software Tool
The already-cleared Ziostation2 (K151212) is the primary predicate device.

**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, Nuclear Medicine, Secondary Capture, Mammography, X-ray Radiofluoroscopic image, RT Image.

**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 validation. Regression testing was also performed on all functionality present on Ziostation2 prior to release. In addition, potential hazards have been addressed by the Ziosoft Risk Management process.

**Summary of Substantial Equivalence**

**Similarities and Differences**

1) Ziostation2 with already cleared aspects

With respect to the already-cleared intended use of Ziostation2, no significant functional differences exist between Ziostation2 and SE K151212. Certain improvements in workflow and usability have been implemented. The function of each tool being improved or added and the difference between it and the current Ziosoft, Inc. Ziostation2 and/or predicate device are discussed in the following items.
2) LAA analysis (Goddard)

LAA analysis (Goddard) is adding Goddard score classification to Ziostation2. The feature of Goddard score classification is legally marketed in SYNAPSE 3D LUNG AND ABDOMEN ANALYSIS K130542. Other features are previously cleared in CT PULMONARY ANALYSIS K130552 including LAA analysis.

3) Lung Lobes

Lung Lobes is adding lung lobes extraction to Ziostation2. The feature of lung lobes extraction is legally marketed in SYNAPSE 3D LUNG AND ABDOMEN ANALYSIS K130542. Other features are previously cleared in CT PULMONARY ANALYSIS K130552.

4) Advanced MPR Batch

Advanced MPR Batch is a workflow enhancement. No significant functional differences exist between SE K151212.

5) Virtual Bronchoscopy

Virtual Bronchoscopy is a new functionality added to Ziostation2. The feature of showing the route to the desired target and showing Virtual Bronchoscopy is legally marketed in SYNAPSE 3D LUNG AND ABDOMEN ANALYSIS K112051 and LUNGPONT PLANNING AND VIRTUAL BRONCHOSCOPIC NAVIGATION (VBN) SOFTWARE. Other features are previously cleared in SE K151212 and CT PULMONARY ANALYSIS K130552. Virtual Bronchoscopy does not communicate with real Bronchoscope.

6) CT Lung Resection Planning

CT Lung Resection Planning is a new functionality added to Ziostation2. The feature of extracting bronchi and lung lobes, extracting lesions and providing the proposal for lung resection are legally marketed in IQQA-BODYIMAGING SOFTWARE K141745 and SYNAPSE 3D LUNG AND ABDOMEN ANALYSIS K130542. Some other lung analysis features are previously cleared in CT PULMONARY ANALYSIS K130552.

7) MR Myocardial T1 Mapping

MR Myocardial T1 Mapping is a new functionality added to Ziostation2, providing analysis of myocardium MR T1 mapping which is legally marketed in SYNGO MR B17 K082427, MR-CT VVA K140587 and ACHIEVA, INTERA AND PANORAMA 1.0T, RELEASE 2.5 K063559.

MR Myocardial T1 Mapping provides post process analysis and does not provide image scanning.

8) Conclusion

With respect to the tools and features offered by Ziosoft, no significant functional differences exist between Ziostation2 software and those portions of the legally marketed SE devices that perform the same functions.