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

May 5, 2020

Re: K200315
Trade/Device Name: Ziostation2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 4, 2020
Received: February 19, 2020

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. 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)*
K200315

Device Name
Ziostation2

Indications for Use *(Describe)*

• This application software 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.

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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510(k) Summary
Ziostation2
Ziosoft, Inc.

This 510(k) summary is prepared in accordance with 21 CFR 807.92. K200315

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
Telephone: +1 (650) 413 1300
E-mail: Dball@ziosoftinc.com

Indications for Use

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

Predicate devices to Ziostation2 Software Tool

Device Name	510(k) Number
Ziostation2	K181892
syngo.CT Dual Energy	K150757
SOMATOM Force	K133589
SOMATOM Definition Flash	K121072

The already-cleared Ziostation2 (K181892) 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.

CT Dual kV is a new image processing tool of Ziostation2
The added capabilities provided by this additional image processing tool for use with CT DICOM compliant images are:
Generating and manipulating further images using volume data of two different tube voltage CT scans:

- Blend image
- Subtraction image
- Virtual non-contrast image
- Iodine distribution map
- 2-Material decomposition 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 indications for use of Ziostation2, no significant functional differences exist between Ziostation2 and SE K181892. The function of tool added and the difference between it and the current Ziostation2 and/or predicate device are discussed in the following items.

2) CT Dual kV

CT Dual kV is a new functionality added to Ziostation2. The feature of generating and manipulating images using volume data of two different tube voltage CT scans is legally marketed in syngo.CT Dual Energy K150757, SOMATOM Force K133589 and SOMATOM Definition Flash K121072. Other features are previously cleared in SE K181892.

3) 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.