Zed Technologies
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

April 12, 2018

Re: K180549
Trade/Device Name: ZED LINK™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2018
Received: March 1, 2018

Dear Mr. Alletto:

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.

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.

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180549

Device Name
ZED LINK™

Indications for Use *(Describe)*
ZED LINK™, is an image management system whose intended use is to provide scalable DICOM compatible PACS solutions for hospitals and related institutions and sites, which will archive, distribute, retrieve and display images and data from all image modalities (such as CR, CT, DR, MR, and other devices) and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation" and will include standard features and other tools for analyzing mammography images. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. 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 that meets technical specification identified by FDA. ZED LINK™, is not intended for diagnostic image review on mobile devices. Typical users of this system are doctors and health care professionals.

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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
March 30, 2018

Submitter's Information: 21 CFR 807.92(a)(1)
Mr. Ronald Li, Co-Founder and CTO
Zed Technologies,
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Tel +61 1300 662 980
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	ZED LINK™
Common Name:	Picture, archive and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological
510(k) Number	K151957
Device Name	BOX DICOM Viewer
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	07/16/2015
Decision Date	09/01/2015
Decision	substantially equivalent (SE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
summary	summary
Reviewed by Third Party	No
Combination Product	No

Device Description: 21 CFR 807 92(a)(4)

ZED LINK™ has four main uses:

- Hard copy replacement: Replaces hard-copy media for managing medical images, such as film archives.
- Remote access: Expands the possibilities of conventional systems by providing capabilities of off-site viewing and reporting (distance education, tele review). It enables practitioners in different physical locations to access the same information simultaneously for teleradiology.
- Electronic image integration platform: Provides the electronic platform for radiology images interfacing with other medical automation systems such as Hospital Information System (HIS), Electronic Medical Record (EMR), Practice Management Software, and Radiology Information System (RIS).

- Radiology Workflow Management: Used by radiology personnel to manage the workflow of patient exams.

Typical Workflow

- The typical Workflow starts when a patient arrives at the Medical Institution: Hospital or diagnostic center to get a radiological exam.
- The Medical Institution could have a modality, like an MRI Machine or X-Ray and start by registering the patient information like name and date of birth.
- Once the patient information is registered, the Modality User (not part of ZED LINK™) can start the acquisition of the images.
- After taking the images, images are on the network and the radiologist can view images using ZED LINK™, add annotations, and write a report.
- Finally, exam can be forwarded, and/or the report viewed by others.
- The figure below shows the typical workflow diagram.

Cyber Security/Web-Based Deployment/Smart Update

The ZED LINK™, is a web-based solution that gives easy accessibility through a web browser and a software update can be automatically performed whenever a user logs in. Therefore, the User will access the latest version of ZED LINK™, with every log-on and reduces the risk of cyber security issues Also, if cyber security issues are found or suspected, the software can be modified and the modification is available the next time the User logs into the system.

Image Distribution & Viewing

- Users can access image data and Viewer tools via Internet at any time.
- Provides user-defined application profile for technicians, radiologists, and outpatient physicians with customized tools for each user type.
- Users can access HIS / RIS data through HL7 interface.
- Provides advanced hanging protocol and worklist tools preset to suit each user; optimal Viewer environment is guaranteed for convenient usage experience.
- With ZED LINK™, roaming profile, users can access PACS Viewer from anywhere and find their personal settings intact.
- Instant, effective communication tool for technicians, radiologists, and emergency physicians, is provided to ensure smoother, quicker treatment process.
- Provides DICOM-compatible Grayscale Softcopy Presentation State [GSPS] which enables important dictation data to be stored and shared in DICOM format without any data loss.
- Automatic updates of name labels on both current and related exams allow for easier analysis.
- Automatic marking of scout lines on selected images; users can quickly and intuitively select scout images.
- Users can easily save and re-access worked images in their current states, using Demo Folder and 2D Job Save function.

Security and Privacy

- TLS DICOM.
- Digital signature.
- Control by user accounts, authority and modality authority.
- Provides accurate inspection information through 6-Level Log Reinforcement & Audit Trail.

- Detailed logs about invalid DICOM IOD.
- Safe and coded web protocol: 128 bit and SSL code available.
- Creates a reliable event log to patient information through user authentication that is compliant with the IHE security profile.
- Through role-based access controls, administrators can define specific permissions and access levels for users and user groups.
- Manages log-in and password to internal and external access.
- Managers can make limitations to every user level via the auto-logoff function.
- Provides inspection, report and statistics compliant with HIPAA security to every record.

Indications for Use: 21 CFR 807 92(a)(5)

ZED LINK™, is an image management system whose intended use is to provide scalable DICOM compatible PACS solutions for hospitals and related institutions and sites, which will archive, distribute, retrieve and display images and data from all image modalities (such as CR, CT, DR, MR, and other devices) and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation" and will include standard features and other tools for analyzing mammography images. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. 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 that meets technical specification identified by FDA. ZED LINK™, is not intended for diagnostic image review on mobile devices. Typical users of this system are doctors and health care professionals.

Technological Characteristics: 21 CFR 807 92(a)(6)

ZED LINK™, is a software application that handles medical digital images. The device does not contact the patient, nor does it control any life sustaining devices.

A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. The universal format for PACS image storage and transfer is DICOM, (Digital Imaging and Communications in Medicine). Non-image data, such as scanned documents, may be incorporated using consumer industry standard formats like PDF (Portable Document Format), once encapsulated in DICOM. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use.

The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The 2 devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use.

The following table compares the predicate device and new device. Any differences between the predicate and the new device has no impact on safety or efficacy of the new device and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Ref #	Functionality	Predicate: BOX DICOM Viewer K151957	Subject Device: ZED LINK™	If different, Impact on Safety and or Efficacy
1	Web Browser	Google Chrome for all features. Microsoft Internet	Our viewer supports Microsoft Internet Explorer, Microsoft	Yes, there are differences. The difference is that the subject device covers additional Web

Ref #	Functionality	Predicate: BOX DICOM Viewer K151957	Subject Device: ZED LINK™	If different, Impact on Safety and or Efficacy
		Explorer & Mozilla Firefox for features except the DICOM Viewer	Edge, Mozilla Firefox, Google Chrome, Apple Safari and Opera for all features.	Browsers and they can be used for all device features.
2	Intended use	Acquiring, viewing, editing and storing radiographs and related patient's images	Same as predicate	No difference
3	Intended user	Radiologist & qualified medical personnel	Same as predicate	No difference
4	Network	10/100/100 Ethernet	Same as predicate	No difference
5	Monitor	Above 19inch monitor (Using 1280x1024)	Same as predicate	No difference
6	User interaction/input	Same, Using 1280x1024	Same as predicate	No difference
7	Import / export images	Yes	Same as predicate	No difference
8	Acquisition devices	CT, MR, US, PET	Same as predicate	No difference
9	Image organization	Patient ID, Name, study instance UID	Same as predicate	No difference
10	Image search available	Same	Same as predicate	No difference
11	Image storage	Yes	Same as predicate	No difference
12	Database software	MySQL	MS SQL	No difference
13	Greyscale Image Rendering	Yes	Same as predicate	No difference
14	RGB Image Rendering	Yes	Same as predicate	No difference
15	Localizer Lines	Yes	Same as predicate	No difference
16	Localizer Point	Yes	Same as predicate	No difference
17	Orientation Markers	Yes	Same as predicate	No difference
18	Distance Markers	Yes	Same as predicate	No difference

Ref #	Functionality	Predicate: BOX DICOM Viewer K151957	Subject Device: ZED LINK™	If different, Impact on Safety and or Efficacy
19	Study Data Overlays	Yes	Same as predicate	No difference
20	Stack Navigation	Yes	Same as predicate	No difference
21	Window Level	Yes	Same as predicate	No difference
22	Zoom in on images	Yes	Same as predicate	No difference
23	Panning	Yes	Same as predicate	No difference
24	Horizontal/Vertical Flip	Yes	Same as predicate	No difference
25	Clockwise/Counterclockwise rotate	Yes	No	Yes, there is a difference. The difference does not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the subject device.
26	Invert image	Yes	Same as predicate	No difference
27	Text Annotation	Yes	Same as predicate	No difference
28	Area measurement annotation	Yes	No	Yes, there is a difference. The difference does not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the subject device.
29	Angle measurement annotation	Yes	Same as predicate	No difference
30	Cobb Angle Measurement Annotation	Yes	Same as predicate	No difference
31	Image annotation	Yes	Same as predicate	No difference
32	Security	Yes	Same as predicate	No difference
33	DICOM 3.0 conformance	Yes	Same as predicate	No difference
34	Worklist	Yes	Same as predicate	No difference

510(k) Summary

Ref #	Functionality	Predicate: BOX DICOM Viewer K151957	Subject Device: ZED LINK™	If different, Impact on Safety and or Efficacy
35	Thumbnail viewing	Yes, thumbnails on preview, small, medium and large	Same as predicate	No difference
36	Login	Yes	Same as predicate	No difference
37	Audit	Yes, a tool to view access logs in real time.	Same as predicate	No difference
38	WebGL rendering optimizations	No hardware acceleration.	Same as predicate	No difference
39	Support for high resolution Retina displays	Pixelated display on high-DPI displays only (i.e., “Retina Displays”).	Same as predicate	No difference
40	Keyboard shortcuts for tools and all annotation types	Limited keyboard shortcut support.	None	Yes, there is a difference. The difference does not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the subject device.
41	Multi-Planar Reconstruction (MPR)	None	Yes, there is a Multi-Planar Reconstruction (MPR) feature. MRP is a technique used in two-dimensional tomographic imaging (computed tomography and magnetic resonance) to generate sagittal, coronal, and oblique views from axial sections.	Yes, there is a difference. The predicate device does not have the MPR feature. The difference has been reviewed as part of the Hazard Analysis and the mitigations were tested. The difference does not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the subject device.

Nonclinical Testing:

The ZED LINK™, system and configuration has been assessed and tested at ZED Technologies PTY. LTD. and has passed all pre-determined testing criteria. The Verification & Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by the ZED LINK™, software in each operational mode and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated, that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met. If the device is installed by ZED Technologies, integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the ZED LINK™, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

510(k) Summary

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The modification to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, the ZED LINK™, device is substantially equivalent to the predicate device.