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

September 2, 2016

XIAN WINGSPAN ELECTRONIC TECHNOLOGY CO., LTD.
% Echo Chou
QA Engineer
Rm. A608, Pioneering Square, No. 48 Keji Rd., Gaoxin Dist.
Xi'an, Shaanxi 710075
CHINA

Re: K162141
Trade/Device Name: Restore PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 3, 2016
Received: August 5, 2016

Dear Echo Chou:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162141

Device Name
Restore PACS

Indications for Use *(Describe)*

Restore PACS is a device that receives digital medical images and data from various sources (such as, MR scanners, CT Scanners, Digital Xray systems, computers, image gateways or other image sources). Images and other medical data can be communicated, processed, managed, manipulated, stored and displayed within the system and/or across computer networks at distributed locations. Typical users of this system are trained radiologists, technicians, clinicians and nurses.

Contraindications:
Restore PACS is contraindicated for the use of lossy compressed mammographic images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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."

SECTION 05: 510(K) SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared: July 29, 2016

Submitter's Information:

Company name Xi'an Wingspan Electronic Technology Co., Ltd.
Address Rm. A608, Pioneering Square, No. 48 Keji Rd., Gaoxin Dist., Xi'an, Shaanxi, China
Contact
Name Echo Chou
Title QA Engineer
Phone number 86-15929949205
Fax number 86-29-88328071-817
Email echo@wingspan.cn

Trade Name, Common Name and Classification:

Name of Device: Restore PACS
Common Name: Picture Archiving and Communication System
Classification: 21 CFR 892.2050, System, Image Processing, Radiological
Regulatory Class: II
Product Code: LLZ

Predicate Device:

Restore PACS is substantially equivalent to:

510(k) Number: K150707
Trade/Device Name: IntelePACS™
Product Code: LLZ
Original Applicant INTELERAD MEDICAL SYSTEMS INCORPORATED
Decision Date May 27, 2015

Device Description:
Restore PACS include features that receives digital medical images and data from various sources (such as, MR scanners, CT Scanners, Digital Xray systems, computers, image gateways or other image sources). Images and other medical data can be communicated, processed, managed, manipulated, stored and displayed within the system and/or across computer networks at distributed locations.
Restore PACS is designed to be deployed over TCP/IP networking infrastructure available in customer sites and utilizes commercially available hardware and operating systems.
The system of Restore PACS does not generate any original medical images. All images in the Restore PACS are received from DICOM compliant systems.

Indications for Use:
Restore PACS is a device that receives digital medical images and data from various sources (such as, MR scanners, CT Scanners, Digital Xray systems, computers, image gateways or other image sources). Images and other medical data can be communicated, processed, managed, manipulated, stored and displayed within the system and/or across computer networks at distributed locations. Typical users of this system are trained radiologists, technicians, clinicians and nurses.

Contraindications:
Restore PACS is contraindicated for the use of lossy compressed mammographic images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Technological Characteristics with Predicate Device:
Restore PACS is a software product that handles and manipulates digital medical images. In general, a PACS (Picture Archiving and Communication System) is a medical imaging technology which provides storage of, and convenient access to, images from multiple modalities. Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM 3.x (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 predicate device and the new device are compared below:

Item	IntelePACS (K150707)	Restore PACS (Subject Device)	Substantial Equivalence Analyses
Workstation Operating System	Windows 7 64-bit Professional	Windows 7 64-bit or 32 bit Professional	Difference – See explanation in A.
Network	10/100/100 Ethernet	10/100/100 Ethernet	Identical

Restore PACS - Traditional 510(k)

User interaction/input	Mouse, keyboard, touch monitor	Mouse, keyboard	Equivalent – Restore PACS does not provide touch monitor
Acquisition devices	CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways	CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways	Identical
Image search	Yes	Yes	Identical
Import/Export Image	Yes	Yes	Identical
Image Archive function	Yes	Yes	Identical
Image View	Yes	Yes	Identical
Image Measurement	Yes	Yes	Identical
Image Annotation	Yes	Yes	Identical
Image Manipulation	Yes	Yes	Identical
Post image data processing	Yes	Yes	Identical
Image Pan	Yes	Yes	Identical
Image Thumbnail viewing	Yes	Yes	Identical
Image Magnify Glass	Yes	Yes	Identical
DICOM 3.0 compatibility	Yes	Yes	Identical
Multi-user	Yes - at a time, only one user can use it	Yes	Identical
Image organization	Patient ID, Name, study instance UID	Yes	Identical
Image operations	Yes	Yes	Identical
Security	Yes (Priority by user)	Yes	Identical
RAW Image data processing	Yes	Yes	Identical
Image reset	Yes	Yes	Identical
panning	Yes	Yes	Identical
Fit image	Yes	Yes	Identical

Server Operating System	Red Hat Enterprise Linux 6, latest Update, for 64-bit x86	Windows Server 2012, Enterprise Edition	See explanation in B
Server Memory	16 Gigabytes	8 Gigabytes	See explanation in B
Server Database	Sybase and PostgreSQL	Microsoft SQL Server 2012, Enterprise Edition.	See explanation in B
WorkStation Processor	Intel 6-core Xeon Processor 3.2GHz	Intel Processor, 2 Cores, 2.0 GHz	See explanation in C
Workstation Memory	6 Gigabytes	4 Gigabytes	See explanation in C

A. Workstation Operating System: Restore PACS has been tested and validated with Windows 7 professional 32 bit and 64bit, the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
B. Restore PACS 2.0 has been tested and validated on server configuration of Windows Server 2012, Enterprise Edition 64 bit, Microsoft SQL Server 2012, Enterprise Edition and 8 G Memory, the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
C. Restore PACS 2.0 has been tested and validated on workstation configuration of Intel Processor, 2 Cores, 2.0 GHz and 4G Memory, the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.

Non-Clinical Testing

The Restore PACS has been assessed and tested at the factory and has passed all in-house testing criteria. The Verification & Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the Restore PACS 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.

The subject of this submission did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

Conclusion

Comparison of the Indications for Use, the technological characteristics, and performance specifications demonstrate the functional equivalence of the subject device to the predicate device. 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.

Nonclinical testing results demonstrate the difference to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. Information provided in this premarket notification submission supports the Restore PACS to be as safe, as effective and substantially equivalent to its predicate device.