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

March 17, 2017

JPI Healthcare Solutions, Inc.
% Mr. William Little
Product Manager
52 Newtown Plaza
PLAINVIEW NY 11803

Re: K162868
Trade/Device Name: Exam Vue PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 3, 2017
Received: March 7, 2017

Dear Mr. Little:

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,

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)*
K162868

Device Name
ExamVue PACS

Indications for Use *(Describe)*
ExamVue PACS is an image management system intended to be used by trained professionals, including physicians, radiologists, nurses and medical technicians.

The software is a software package used with general purpose computing hardware to receive, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage. This device is not indicated for use in mammography.

ExamVue PACS supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CR and DX.

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

February 28th, 2017.

1. Company and Correspondant Making the Submission:

Name: JPI Healthcare Co,. LTD
Address: Woolim e-BIZ center #608
170-5, Kuro-3-dong, Kuro-gu
Seoul, 152-769
Telephone: +82-2-2108 - 2580 (Ext. 500-504)
Fax: +82-2-2108-1180
Contact: John Lim
Website: http://www.jpi.co.kr/

2. Identification of Device

Classification Name: Imaging Processing System, Radiological
Common Name: Picture Archiving and Communication System (PACS)
Trade/Proprietary Name: ExamVue PACS

3. Predicate Device

Manufacturer: Vieworks Co, Ltd
Device: QXLink
510(k) Number: K092081
Classification Name: Imaging Processing System, Radiological
Common Name: Picture Archiving and Communication System (PACS)
Regulatory Number: 21 CFR 892.2050
Regulatory Class: II
Product Code: 90 LLZ

Manufacturer: Televere
Device: Tigerview Professional
510(k) Number: K061035
Classification Name: Imaging Processing System, Radiological
Common Name: Picture Archiving and Communication System (PACS)
Regulatory Number: 21 CFR 892.2050
Regulatory Class: II
Product Code: 90 LLZ

4. Product Classification Names and Citations

Classification Name: Imaging Processing System, Radiological
Common Name: Picture Archiving and Communication System (PACS)
Regulatory Number: 21 CFR 892.2050
Regulatory Class: II
Product Code: 90 LLZ

5. Description:

The ExamVue PACS is a software solution for the storage, sharing, display and viewing for diagnosis of medical images. It consists of two software components, a central database and server software that holds, receives and distributes images, and a viewer program that can be installed on multiple computers for viewing, modifying, making measurements on, and displaying the images in the database.

6. Indication for use

ExamVue PACS is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.

The software is a software package used with general purpose computing hardware to receive, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage. This device is not indicated for use in mammography.

ExamVue PACS supports receiving, sending, printing, storing and displaying studies received from the following modality type via DICOM: CR and DX.

7. Comparison with Predicate Device:

JPI Healthcare Co., Ltd, believes that the ExamVue PACS is substantially equivalent to the predicate devices, TigerView Professional and QXLink

All three devices have the same basic structure (a central server database and associated viewers), function (the storage, display and diagnosis of DICOM images) and follow the DICOM protocol. They have similar intended uses, and provide similar suites of tools to fulfil their function.

The ExamVue PACS differs from the predicate devices is user interface and compatible operating systems. We believe this does not represent a substantial difference between the two devices, as the change in system requirements reflect the change in computer technology since the release of the predicate device, and the user interface presents the same essential data and supports similar workflow as the predicate device.

8. Safety, EMC and Performance Data

   Safety testing and documentation was performed in accordance with IEEE 1012-2012, Standard for System and Software Verification and Validation.

   Software Verification and Validation documentation for ExamVue PACS, as well as bench and clinical testing, have been provided in this submission.

9. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification JPI Healthcare Co., Ltd. concludes that ExamVue PACS is safe and effective and substantially equivalent to predicate devices as described herein.

   A detailed comparison supporting this conclusion can be found in Exhibit 1, Substantial Equivalence Chart below.

EXHIBIT 1

SUBSTANTIAL EQUIVALENCE CHART

Characteristics	**ExamVue PACS**	TigerView Professional	QXLink
Manufacturer	JPI Healthcare Solutions, Inc	Televere Systems	Vieworks Co, Ltd
510K Number	K162868	K001035	K092081
Intended use.	ExamVue PACS is an image management system intended to be used by trained professionals, including physicians, radiologists, nurses and medical technicians. The software is a software package used with general purpose computing hardware to receive, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage. This device is not indicated for use in mammography. ExamVue PACS supports receiving, sending, printing,	TigerView Professional is a clinical software application that receives images and data from various imaging sources (eg., radiographic devices, digital video capture device, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes and clinical exam data. It is intended to acquire, display, edit(e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware	The QXLink is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components provide functions for performing operations related to image manipulation, enhancement, or quantification.DICOM 3.0 standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.0 by using DICOM and Network systems.

	storing and displaying studies received from the following modality types via DICOM: CR and DX.		
Performance Standard	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Operating System Requirements	Windows 7 or Windows 8 or Windows 10	Windows Based Operating Systems	Windows Based Operating Systems
Image Archive	Yes	Yes	Yes
Image Transfer	Yes (DICOM 3.0 Standard)	Yes (DICOM 3.0 Standard)	Yes (DICOM 3.0 Standard)
Image Display	Yes	Yes	Yes
Patient Search	Yes	Yes	Yes
Distance and Angle Measurements	Yes	Yes	Yes
Window Level Adjustment	Yes	Yes	Yes
Zoom and Magnify Functions	Yes	Yes	Yes
Line Profile and Histogram	Yes	Yes	Yes
DICOM Directory Reading	Yes	No	Yes
DICOM Query/Retrieve	Yes	No	Yes
DICOM Import	Yes	Yes	Yes
DICOM CD Burn	Yes	Yes	Yes
DICOM Print	Yes	Yes	Yes
DICOM Tag Display	Yes	Yes	Yes
Patient Information Editing	Yes	Yes	Yes

The intended use and environment of the device is the same as the predicate devices, with only minor differences in features that are not integral to the function of the device. For this reason, we believe it is substantially equivalent to the predicate devices.