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

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

April 17, 2015

Re: K142930
Trade/Device Name: ExamVue DR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 2, 2015
Received: April 3, 2015

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K142930

Device Name
ExamVue DR

Indications for Use *(Describe)*
ExamVue DR is a software for the acquisition, processing, storage and viewing of two-dimensional digital radiology images. ExamVue DR is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects. ExamVue DR is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems.

ExamVue DR is not indicated for use in mammography.

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

May 20, 2014

1. Company and Correspondant Making the Submission:

Name: JPI Healthcare Co,. LTD
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Fax: +82-2-2108-1180
Contact: Wonsik (Stanly) Youn
Website: http://www.jpi.co.kr/

2. Identification of Device

Classification Name: System, Image Processing, Radiological
Common Name: Digital X-ray Acquisition Software
Trade/Proprietary Name: ExamVue DR

3. Predicate Device

Manufacturer: IMFOU Co, Ltd
Device: feel-DRCS
510(k) Number: K110033

4. Product Classification Names and Citations

Regulatory Number: 21 CFR 892.1680
Regulatory Class: II
Product Code: 90 KPR

5. Description:

The ExamVue DR software is designed for use by radiologists and radiology technicians for the acquisition of digital x-ray images. It interfaces with 3rd party digital x-ray detectors or CR scanners and manufacturer supplied software for the acquisition and storage of digital x-ray images. The ExamVue software then provides a user interface for the viewing, annotating, and other workstation functions. ExamVue DR includes the ability to receive patient information and send x-ray images to remote destinations using the DICOM 3.0 protocol.

6. Indication for use

ExamVue DR is a software for the acquisition, processing, storage and viewing of digital x-ray images. ExamVue DR is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems.

ExamVue DR is not indicated for use in mammography.

7. Comparison with Predicate Device:

JPI Healthcare Co., Ltd, believes that the ExamVue DR software is substantially equivalent to the feel-DRCS software of IMFOU.

The ExamVue DR software and the predicate device both

-Provide a user interface for the registration, acquisition, and evaluation of x-ray studies.

-Perform the functions of image transfer, image acquisition, image processing, and maintaining a patient database.

-Use the DICOM 3.0 standard for medical imaging

-Are intended for installation on Windows operating systems for use in a medical environment.

-Interface with and process images from multiple models of hardware.

ExamVueDR and the predicate device share the same essential functions of image acquisition, transfer, and processing; however they have different user interfaces and different computer hardware and operating system requirements. 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.

7. 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.

We have also provided performance and clinical testing using example X-ray detectors, as recommended by the FDA guidance document "Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices"

8. 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 DR is safe and effective

and substantially equivalent to predicate devices as described herein.