February 18, 2022

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

Re: K213057
Trade/Device Name: ExamVue Duo
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: February 8, 2022
Received: February 10, 2022

Dear William 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. 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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213057

Device Name
ExamVue Duo

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

ExamVue Duo 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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K213057

510 (k) Summary

April 12, 2021

1. Company and Correspondant Making the Submission:

Name: JPI Healthcare Co,. LTD
Address: 608-ho, 28, Digital-ro 33-gil, Guro-gu, 08377 Seoul, Korea
Telephone: +82-2-2108 - 2580
Fax: +82-2-2108-1180
Contact: Lee Jang Won
Website: http://www.jpi.co.kr/

2. Identification of Device

Classification Name: Stationary x-ray system
Common Name: Digital X-ray Acquisition Software
Trade/Proprietary Name: ExamVue Duo

3. Predicate Device

Manufacturer: JPI Healthcare Solutions, Inc
Device: ExamVue DR
510(k) Number: K142930
Classification Name: Stationary x-ray system
Common Name: Digital X-ray Acquisition Software
Regulatory Number: 21 CFR 892.1680
Regulatory Class: II
Product Code: 90 KPR

4. Product Classification Names and Citations

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

5. Description:

The ExamVue Duo 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 and (optionally) generators and manufacturer supplied software for the acquisition and storage of digital x-ray studies. The ExamVue Duo 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 studies to remote destinations using the DICOM 3.0 protocol.

6. Indication for use

ExamVue Duo is a software for the acquisition, processing, storage and viewing of digital radiology studies. ExamVue Duo is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects.
ExamVue Duo is indicated for use in general imaging, specialist imaging including podiatry, orthopedic, and other specialties, and in mobile x-ray systems.

ExamVue Duo is not indicated for use in mammography.

7. Comparison with Predicate Device:

JPI Healthcare Co., Ltd, believes that the ExamVue Duo software is substantially equivalent to the ExamVue DR software registered by JPI Healthcare Co. Ltd
The ExamVue Duo 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.

ExamVue Duo and the predicate device share the same essential functions of image acquisition, transfer, and processing; however they have different user interfaces and ExamVue Duo has some additional registration, annotation and imaging processing features. We believe this does not represent a substantial difference between the two devices, as the user interface presents the same essential data and supports similar workflow as the predicate device.

8. Safety, EMC and Performance Data

Bench tests reports and clinical data have been provided, detailing the direct comparison of functions between the ExamVue Duo and predicate device.

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 the 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.

EXHIBIT 1

SUBSTANTIAL EQUIVALENCE CHART

Characteristics	**Proposed** **ExamVue Duo**	**Predicate 1** **ExamVue DR**
Manufacturer	JPI Healthcare Solutions, Inc	JPI Healthcare Solutions, Inc
510(k) Number		K142930
Intended use.	The ExamVue Duo 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 Duo software then provides a user interface for the viewing, annotating, and other workstation functions. ExamVue Duo software includes the ability to receive patient information and send x-ray images to remote destinations using the DICOM 3.0 protocol.	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 DR 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.
Performance Standard	21 CFR 820 21 CFR 830	SAME
Processor	Intel Core i5 or higher	Intel Core i5 or higher
RAM	8GB or higher	Min. 4GB
Hard Disk	Min. 500GByte	Min. 500GByte

Network	1GBit	1GBit
Operating System Requirements	Windows 10	Windows 7, Windows 8 or Windows 10
Resolution	Min. 1366 x 768	1920 x 1080
Image Transfer	DICOM 3.0 Standard	Same
Image Acquisition	Yes	Yes
Image Processing	Yes	Yes
Windowing	Yes	Yes
Image Formatting	Yes (1x1, 1x2, 2x1, 2x2, 3x3)	Yes (1x1, 1x2, 2x1, 2x2, 3x3)
Annotations and Measurements	Yes	Yes
Image Rotation	Yes	Yes
Zoom	Yes	Yes
Patient Database	Yes	Yes
DICOM Worklist	Yes	Yes
DICOM Store	Yes	Yes
DICOM Print	Yes	Yes
Detector Specific	No	No

X-ray Generator Control	Yes	Yes
SW Ver.	ExamVue Duo – 1.0	ExamVue DR - 1.0
Added Functions	- Auto Stitching - Bone Suppression (option) - Chiropractic measurement features (option) - Podiatry measurement tools (option)	

Summary

- The pre / post image processing algorithm is the same for ExamVue DR and ExamVue Duo.
- The measurement features for Chiropractic and Podiatry in ExamVue Duo are additional features. However, they are similar to the measurement function of length and angle already incorporated in ExamVue DR (Ver 1.0). For the user convenience, a specific region of interest for chiropractic and podiatry was designated as a dedicated in ExamVue Duo (Ver 1.0).
- In Conclusion, 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. The differences do not introduce a fundamentally new scientific technology.

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.