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

October 28, 2016

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

Re: K160143
Trade/Device Name: ClearVision Exam Vue Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 12, 2016
Received: September 13, 2016

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)*
K160143

Device Name
ClearVision ExamVue Flat Panel Detector

Indications for Use *(Describe)*
The ClearVision ExamVue Flat Panel detector is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems.
The ClearVision ExamVue Flat Panel detector 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

August 10, 2016.

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: Solid State X-ray Imager (flat panel/digital imager)
Common Name: Solid State X-ray Imager
Trade/Proprietary Name: ClearVision ExamVue Flat Panel Detector

3. Predicate Device

Manufacturer: Atlaim
Device: ATAL-8
510(k) Number: K113812
Classification Name: Solid State X-ray Imager (flat panel/digital imager)
Common Name: Solid State X-ray Imager
Regulatory Number: 21 CFR 892.1680
Regulatory Class: II
Product Code: 90 MQB

Manufacturer: Samsung Mobile Display
Device: DIGITAL FLAT PANEL X-RAY DETECTOR, MODEL LTX240AA01-A
510(k) Number: K090742
Classification Name: Solid State X-ray Imaging Device
Common Name: Digital Flat Panel Xray Detector
Regulatory Number: 21 CFR 892.1680
Regulatory Class: II
Product Code: 90 MQB

4. Product Classification Names and Citations

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

5. Description:

The ClearVision ExamVue Flat Panel Detector consists of a line of 3 different models of solid state x-ray detectors, of differing size and characteristics, designed for use by radiologists and radiology technicians for the acquisition of digital x-ray images. The ClearVision ExamVue Flat Panel Detector captures digital images of anatomy through the conversion of x-rays to electronic signals, eliminating the need for film or chemical processing to create a hard copy image. The ClearVision ExamVue Flat Panel Detector incorporates the ExamVueDR software, which performs the processing, presentation and storage of the image in DICOM format.

All models of the ClearVision ExamVue Flat Panel Detector use aSi TFTD for the collection of light generated by a CsI scintillator, for the purpose of creating a digital x-ray image. The three available models are:

a. A 14x17in (35x43cm) tethered cassette sized panel
b. A 14x17in (35x43cm) wireless cassette sized panel with automatic exposure detection
c. A 17x17in (43x43cm) tethered panel for fixed installations.

6. Indication for use

The ClearVision ExamVue Flat Panel Detector is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems.

The ClearVision ExamVue Flat Panel Detector is not indicated for use in mammography.

7. Comparison with Predicate Device:

JPI Healthcare Co., Ltd, believes that the ClearVision ExamVue Flat Panel Detector is substantially equivalent to the ATAL-8 detector of Atlaim and the LTX240AA01-A of Samsung Mobile Display, Ltd.

The ClearVision ExamVue Flat Panel Detectors have similar or superior characteristics to the predicate devices, including:

a. The same aSi TFTD technology, converting visible light from a scintillator into a digital image.
b. Similar pixel pitch (140um-143um for the ClearVision ExamVue Flat

Panels vs 139um-143um for the predicate devices)

c. Exclusively CsI scintillators, compared to the option of CsI or the lower performance Gadolinium Oxide scintillator in the predicate devices.
d. Similar indications for use, focused on general radiography and excluding mammography.
e. Have been integrated to function with the same image acquisition software, ExamVueDR, for final processing and presentation.

Clinical images were provided; these images were not necessary to establish equivlance based on the modifications to the device (x-ray detector technology identical to predicate devices) but they provide further evidence in addition to the laboratory performance data to show that the subject device works as intended.

The image acquisition control interface testing was performed as part of laboratory and clinical testing. This control interface consists of hard wired control signal to the x-ray generator (all models) or AED (FDX3543RPW). The software control interface for exposure settings on selected generators had been previously tested in the notification of the ExamVueDR software as a stand-alone product (K142930).

8. Safety, EMC and Performance Data

Bench tests reports have been provided, detailing the safety and EMC testing, as well as non-clinical performance data for the ClearVision ExamVue Flat Panel Detector.

Biocompatibility data has been provided for patient-contacting surfaces of the device, demonstrating that there are no known adverse reactions to skin contact with the device.

We have also provided clinical testing of the hardware, showing comparison images using identical software, 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"

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 ClearVision ExamVue Flat Panel Detector 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

| **Device Name** | **ExamVue FPD FDX3543RP** | **Examvue FPD FDX3543RPW** | **Examvue FPD FDX4343R** | **ATAL-8** | LTX240AA01-A |
|---|---|---|---|---|---|
| **Manufacturer** | Toshiba | Toshiba | Toshiba | ATLAIM | Samsung Mobile Display |
| **FDA 510(k) K#** | K160143 | K160143 | K160143 | K113812 | K090742 |
| Intended use. | The ClearVision ExamVue Flat Panel detector is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems.<br><br>The ClearVision ExamVue Flat Panel detector is not indicated for use in mammography. | | | The ATAL 8 and ATAL 8C are indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications. | LTX240AA01-A digital flat panel X-ray detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment palnning for physicians and other health care professionals. Not to be used for mammography. |
| Configuration | This submission is for the digital panel and | | | This | This |

| | | | | | |
|---|---|---|---|---|---|
| | software only, no generator or stand provided. | | | submission is for the digital panel only, no generator or stand provided. | submission is for the digital panel only, no generator or stand provided. |
| Detector Type | Amorphous Silicon (a-Si) Photodiode | | | SAME | SAME |
| Pixel Pitch | 143um | 140um | 143um | 139um | 143um |
| Limiting Resolution | 3.7lp/mm | 3.7lp/mm | 3.7lp/mm | Over 3lp/mm | 3lp/mm |
| A/D Conversion | 16 bit | 14 bit | 14 bit | 14 bit | 14 bit |
| Active Area | 14x17 inch | 14x17 inch | 16.9x17.3 inch | 17x17 inch | 17x17 inch |
| Dimensions (mm) | 384(w) x 460(D) x 15(H) | 384(w) x 460(d) x 15(h) | 512(w) x 495(d) x 43(h) | 500(w) x 500(l) x 25(h) | 500(w) x 497(l) x 44mm (H) |
| Weight | 3kg | 3kg | 9kg | 7.8kg | 13.4kg |
| Pixels | 2448x2984 (7.3Mpx) | 2466x3040 (7.5Mpx) | 3008x3072 (9.2Mpx) | 3072x3072 (9.4Mpx) | 3072x3072 (9.4Mpx) |
| DQE @ 1 lp/mm | 57% | 60% | 58% | 33% Gadox / 46% CsI | 45% Gadox / 65% CsI |
| MTF @ 1 lp/mm | 63% | 68% | 65% | 63% Gadox / 72% CsI | 57% Gadox / 59% CsI |
| DICOM | Yes | Yes | Yes | Yes | Yes |
| Scintillator | CsI | CsI | CsI | CsI/Gadox | CsI/Gadox |
| Interface | Gigabit Ethernet | Gigabit Ethernet or Wireless | Gigabit Ethernet | Gigabit Ethernet | Gigabit Ethernet |
| Automatic Exposure Detection | No | Yes | No | Yes | No |
| Generator Exposure Trigger or Sensor | Yes | Yes | Yes | Yes | Yes |
| Power Source | AC Line | AC Line | AC Line | AC Line | AC Line |
| Standards | Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2. | Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2. | Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2. | Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2. | Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2. |
| Acquisition and Control Software | Exclusively ExamVueDR (K142930) | Exclusively ExamVueDR (K142930) | Exclusively ExamVueDR (K142930) | *Option for ExamVueDR (K142930) | *Option for ExamVueDR (K142930) |

*: The ExamVueDR software 510(k) notification (K149230) includes the indicated detector as one of the detectors the software can be integrated with to form a retrofit solution. The ExamVueDR software is not referenced in the 510(k) notification for the detector itself.

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 image acquisition and user interface software in the device has been previously 510(k) notified for use with the predicate devices. For this reason, we believe it is substantially equivalent to the predicate devices.