February 24, 2025

JPI Healthcare Co, Ltd
% William Little
Senior Product Manager
JPI Healthcare Solutions, Inc
3555 Veterans Memorial Highway Unit D
RONKONKOMA NY 11779

Re: K244010
Trade/Device Name: ExamVue Apex
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: October 2, 2024
Received: December 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244010

Device Name
ExamVue Apex

Indications for Use *(Describe)*

The ExamVue Apex flat panel x-ray detector system is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems. The ExamVue Apex flat panel x-ray detector system 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.

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."

510(k) Summary

ExamVue Apex Digital X-ray Detector

K244010

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 System
Trade/Proprietary Name: ExamVue Apex

3. Predicate Device

Manufacturer: JPI Healthcare, Inc
Device: ClearVision ExamVue Flat Panel Detector
510(k) Number: K160143
Classification Name: Stationary x-ray system
Common Name: Digital X-ray System
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 ExamVue Apex flat panel x-ray detector system consists of a line of 3 different models of solid state x-ray detectors, of differing size and characteristics, combined with a single controlling software designed for use by radiologists and radiology technicians for the acquisition of digital x-ray images. The ExamVue Apex flat panel x-ray detector system 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. ExamVue Apex flat panel x-ray detector system incorporates the ExamVue Duo software, which performs the processing, presentation and storage of the image in DICOM format. All models of the ExamVue Apex flat panel x-ray detector system use a Si 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:
EVA 14W, with a 14x17in (35x43cm) wireless cassette sized panel
EVA 17W, with a 17x17in (43x43cm) wireless cassette sized panel
EVA 10W, with a 10x12 (24x30cm) wireless cassette sized panel

6. Indication for use

The ExamVue Apex flat panel x-ray detector system is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems. The ExamVue Apex flat panel x-ray detector system is not indicated for use in mammography.

7. Comparison with Predicate Device:

JPI Healthcare Co., Ltd, believes that the ExamVue Apex is substantially equivalent to the ClearVision ExamVue Flat Panel Detector registered by JPI Healthcare Co. Ltd.
The ExamVue Apex and the predicate device both
-Are a combination of a digital x-ray detector with an image acquisition software
-Include digital x-ray detectors that are built upon the same fundamental technology (Amorphous Silicon collectors and Cesium Iodide scintillator) to turn incoming x-rays into a digital image.
-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 Apex and the predicate device share the same essential functions of image acquisition, transfer, and processing. The detector hardware differs in resolution and the substrate material for the electronics. The software on the ExamVue Apex is ExamVue Duo, previously registered with 510(k) number K213057 for use with flat panel detectors. The software represents a moderate level of concern, which is addressed in the software validation and verification and bench testing provided with the submission. The software performs the same functions as the software for the predicate device with some additional features, including expanded tool sets to simplify measurement and image viewing and management tools, that do not impact the core functions of the device.
We believe these differences do not represent a substantial difference between the two devices, as the indications for use, core technologies, and user interface presents the same essential data and supports similar workflow as the predicate device.

8. Non-Clinical Test Summary

a) Electrical Safety, Electromagnetic Compatability and Performance
The ExamVue Apex Digital X-ray Detectors comply with voluntary standards for electrical safety, electromagnetic compatibility and product design. Safety and quality testing and documentation have been performed and provided following IEC standards.

Standards No	**Standards Title**	**Version**	**Publication Year**
ISO 10993	Biological Evaluation of Medical Devices	2018	2018
IEC 60529	Degrees of protection provided by enclosures (IP Code)	IEC 60529:1989+ AMD1:1999+ AMD2:2013 CSV	2019
IEC 62304	Medical device software - Software life cycle processes	IEC 62304 Ed. 1.1	2015
IEC 62366	Medical devices - Part 1: Application of usability engineering to medical devices	IEC 62366-1 Ed. 1.1 b:2020	2020

IEC 60068-2-27	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	IEC 60068-2-27 Ed. 4.0 b:2008▹	2008
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2 Ed. 4.1 en:2020	2020
IEC 60601-1-3	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 CSV	2021
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 CSV	2020
IEC 60601-1-8	mendment 2 - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IEC 60601-1-8:2006/AMD2:2020	2020
IEC 60601-2-54	Medical electrical equipment - Part 2-54: Particular requirements for	IEC 60601-2-54:2022	2022

	the basic safety and essential performance of X-ray equipment for radiography and radioscopy		
IEC 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)	IEC 61000-3-2:2018	2018
IEC 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection	IEC 61000-3-3:2013+AMD1:2017+AMD2:2021 CSV	2017
61000-4-2	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	IEC 61000-4-2:2008	2008
IEC 61000-4-3	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	IEC 61000-4-3:2020	2020
IEC 61000-4-4	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity	IEC 61000-4-4:2012	2012

	test		
IEC 61000-4-5	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	IEC 61000-4-5:2014	2014
IEC 61000-4-6	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	IEC 61000-4-6:2023	2023
IEC 61000-4-8	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	IEC 61000-4-8:2009	2009
IEC 61000-4-11	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase	IEC 61000-4-11:2020	2020
IEC 61000-4-39	Electromagnetic compatibility (EMC) - Part 4-39: Testing and measurement techniques - Radiated fields in close proximity - Immunity test	IEC 61000-4-39:2017	2017
IEC 60950-1	Information technology equipment - Safety - Part 1: General requirements	IEC 60950-1 Ed. 2.2 b:2013	2013

	CONSOLIDATED EDITION		
IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	IEC 62133-2:2017	2017
IEC 62304	Medical device software - Software life cycle processes	IEC 62304 Ed. 1.1 b:2015	2015
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	IEC 62366-1 Ed. 1.1 b:2020	2020

b) Additional bench testing was performed detailing the direct comparison of functions between the ExamVue Apex and predicate device. These testing demonstrated that the product performs with similar or greater imaging characteristics
   i) Resolution
   ii) Sensitivity
   iii) Dynamic range in image acquisition
   iv) That the software performs the same required basic functions as the predicate device.

c) Software Validation
   The ExamVue Apex Digital X-ray Detectors contain software of a MODERATE level of concern. The software was designed and developed according to a software development process in compliance with IEC 62304 and tested to show that it performs all the functions of the software in the predicate device. Software development and testing documentation has been provided in accordance with the FDA guidance “The Content of Premarket Submissions for Software Contained in Medical Devices.”

d) Cybersecurity

Cybersecurity documentation and procedures have been provided according to the FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

e) Clinical Testing

Clinical data was provided with the submission to demonstrate equivalence with the predicate device. This data includes images of all the relevant ROI. The images were evaluated by an ABR certified radiologist who evaluated the image quality to be of equivalent or better to the predicate device.
In conclusion, the clinical testing indicate adequate imaging performance of the ExamVue Apex Digital X-ray Detectors.

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 Apex 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 Apex**	**ClearVision ExamVue FPD**
Hardware Manufacturer	Thales	Toshiba
Software Manufacturer	JPI Healthcare Co, Ltd	JPI Healthcare Co, Ltd
FDA 510(k)	K244010	K160143
Models	EVA 10W/ EVA 14W/ EVA 17W	1417T / 1417W / 1717
Intended Use	The ExamVue Apex flat panel x-ray detector system is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile	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 ExamVue Apex flat panel x-ray detector system is not indicated for use in mammography.	x-ray systems. The ClearVision ExamVue Flat Panel detector is not indicated for use in mammography.
Configuration	This submission is for a digital panel and software. It is intended for use with unconnected or software integrated x-ray generators and associated equipment.	This submission is for the digital panel and software only, no generator or stand provided.
Detector Type	Amorphous Silicon	Amorphous Silicon
Pixel Pitch (um)	99	143 / 140 / 143
A/D Conversion (bits)	16	16 / 14 / 14
Active Area	222x285mm 345x425mm 423x423mm	14x17 inch 14x17 inch 16.9x17.3 inch
Dimensions (mm)	267.5(W) x 327.5(D) x 15(H) 383.5(W) x 459.5(D) x 15(H) 459.5(W) x 459.5(D) x 15(H)	384(W) x 460(D) x 15(H) 384(W) x 460(D) x 15(H) 512(W) x 495(d) x 43(h)
Weight (kg)	1.6 / 2.6 / 3	3 / 3/ 9
DQE @ 0 lp/mm	73 % @ 6 µGy / 70 % @ 2 µGy	57% / 60% / 58%
MTF @ 1 lp/mm	68%	63% / 68% / 65%
DICOM Functionality	Yes	Yes
Scintillator	CsI	CsI
Interface	Wifi (802.11ac/ax) or cable	Gigabit Ethernet or Wireless
Automatic Exposure Detection	Thales Full-Field AED	Yes
Generator Exposure Trigger or Sensor	Optional	Yes
Power Source	AC Line	AC Line
Acquisition and Control Software	ExamVue Duo (K213057)	ExamVueDR (K142930)

Summary

- The software used in ExamVue Apex is the direct successor of the ExamVueDR software used in the predicate device, including similar image acquisition,

processing, and other features. Both softwares are independently registered with 510(k) submissions.

- The new features for general medicine, chiropractic and podiatry applications in ExamVue Apex are additional features not included in the predicate device. However, they are similar to the image management and measurement functions already incorporated in the software for the predicate device and are included in the previously registered 510(k) for the included software.
- 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.