November 4, 2025

Vieworks Co., Ltd.
℅ Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman STE 160
IRVINE, CA 92612

Re: K251410
    Trade/Device Name: VXvue
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Medical Image Management And Processing System
    Regulatory Class: Class II
    Product Code: LLZ
    Dated: April 25, 2025
    Received: October 2, 2025

Dear Priscilla Chung:

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

Indications for Use

510(k) Number *(if known)*
K251410

Device Name
VXvue

Indications for Use *(Describe)*

VXvue is intended to acquire Digital images from X-ray Detectors, process the images to facilitate diagnosis and to display, and transfer the resulting images to other devices for diagnostic purpose.

VXvue is indicated for use in general radiographic images of human anatomy. And it is not for fluoroscopic, angiographic, and mammographic applications.

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.

510(k) Summary

(K251410)

This 510(k) summary information is prepared in accordance with 21 CFR807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

Oct 31, 2025

2. Submitter's Information [21 CFR 807.92(a) (1)]

Name of Sponsor:	Vieworks Co., Ltd.
Address:	41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea
Contact Name:	Park, Serin / Regulatory Affairs Associate
Registration Number:	3006013411
Name of Manufacturer:	Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

Trade Name:	VXvue
Model Name:	VXvue
Common Name:	Image Acquisition Software
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.2050
Product Code:	LLZ
Device Class:	2

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

510(k) Number:	**K231225**
Trade Name:	EConsole1
Model Name:	EConsole1
Common Name:	Radiological Image Processing System
Classification Name:	System, Image Processing, Radiological
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.2050
Product Code:	LLZ
Device Class:	2

5. Description of the Device [21 CFR 807.92(a) (4)]

VXvue gets images from a detector, processes, and transfers the images and manages patient's information and the images for radiologists. VXvue enables images such as x-ray images to be stored electronically and viewed on screens.

VXvue offers full compliance with DICOM (Digital Imaging and Communications in Medicine) standards to allow the sharing of medical information with other PACS (Picture Archiving and Communication System Server). Besides, VXvue 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 and enhancement.

6. Indications for Use [21 CFR 807.92(a)(5)]

VXvue is intended to acquire Digital images from X-ray Detectors, process the images to facilitate diagnosis and to display, and transfer the resulting images to other devices for diagnostic purpose.

VXvue is indicated for use in general radiographic images of human anatomy. And it is not for fluoroscopic, angiographic, and mammographic applications.

7. Technological Characteristics [21 CFR 807.92(a) (6)]

Comparisons with the predicate, VXvue shows the technological characteristics substantially equivalent to the predicate device. The proposed device is functionally identical to the predicate device.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate/reference device, VXvue presented in this submission has equivalent:

  • Indications for Use
  • Technological Characteristics

Parameter	Subject Device	Predicate Device	Equivalence
510(k) Number	K251410	K231225	
Manufacturer	Vieworks Co., Ltd.	DRTech Corporation	-
Device Name	VXvue	EConsole1	-
Common Name	Image Acquisition Software		Equivalent
Classification Name	System, Image Processing, Radiological		Equivalent
Classification Panel	Radiology		Equivalent
Classification Regulation	21 CFR 892.2050		Equivalent
Product Code	LLZ		Equivalent
Device Class	2		Equivalent
Acquisition Device	Digital X-ray Detector		Equivalent

Indications of Use	VXvue is intended to acquire Digital images from X-ray Detectors, process the images to facilitate diagnosis and to display, and transfer the resulting images to other devices for diagnostic purpose. VXvue is indicated for use in general radiographic images of human anatomy. And it is not for fluoroscopic, angiographic, and mammographic applications.	**EConsole1** is 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). The main features of this software are controlling and interfacing the detector, controlling the x-ray generator acquisition settings, storing acquired images, data management and image processing.	Equivalent
Technology Characteristic	**VXvue** is an Image Acquisition Software. Its software function is: - Viewing - Processing - Enhancement - Transfer - Annotation - Measurement - Stitching - Storage The device is DICOM compliant and allows the user to transmit and receive data with the PACS system. It does not have control over exposure, electrical changes, or the calibration of the X-ray system.	**EConsole1** is an Image Acquisition Software. Its software function is: - Viewing - Processing - Searching - Annotation - Measurement - Stitching - Storage The device is DICOM compliant and allows the user to transmit and receive data with the PACS system. It does not have control over exposure, electrical changes, or the calibration of the X-ray system.	Equivalent

9. Summary of Non-Clinical Data

Essential Performance

As a result of image evaluation of Resolution, Low Contrast, Dynamic range, and Signal Calibration by processing the DIGRAD Chart image, all criteria were satisfied.

Image quality through image processing, which is the main function of VXvue Intended Use, satisfies the standard.

Software Verification and Validation

As part of this submission, documentation for a medical device software has been provided at the Basic Documentation Level, in accordance with the FDA guidance document titled "Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff" (June 2023). This current software guidance has been reviewed, and we confirm that all software documentation and testing address all applicable elements of the updated software guidance.

The submitted data demonstrates that the medical device containing software consistently meets the applicable special controls. During the development of VXvue, various non-clinical tests such as code testing, module testing, and integration testing were conducted. A risk analysis was performed, and risk control measures were implemented to mitigate identified hazards.

The test results indicate that all software specifications meet the predefined acceptance criteria, and the software verification and validation testing were deemed appropriate, thereby supporting the claim of substantial equivalence for VXvue.

Cybersecurity

VXvue follows the FDA guidance titled " Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff" (June 2025), in order to maintain confidentiality, integrity, and availability.

10. Summary of Clinical Data

Clinical studies are unnecessary to validate the safety and effectiveness of the software in VXvue, the subject of this 510(k) notification.

11. Conclusion [21 CFR 807.92(b) (3)]

The subject device is substantially equivalent to the currently marketed and predicate device (K231225) in terms of fundamental scientific technology, indications for use, and safety and effectiveness.

VXvue passed all Verification and Validation testing, which means that the features, functions, and technology were all demonstrated to perform well. Performance data also demonstrates that VXvue is both safe and effective in its intended performance.

Therefore, VXvue does not introduce any new potential safety risks and is substantially equivalent to the predicate device.