January 16, 2025

Vieworks Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA Inc.
18881 Von Karman Ave, STE 160
Irvine, California 92612

Re: K241113
Trade/Device Name: VIVIX-M
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: October 18, 2024
Received: October 18, 2024

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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)*
K241113

Device Name
VIVIX-M

Indications for Use *(Describe)*
VIVIX-M detectors are flat panel detectors used in mammographic applications to acquire digital images for screening and diagnosis.

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

(K241113)

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

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

1/15/2025

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

Name of Sponsor:	Vieworks Co., Ltd.
Address:	(Gwanyang-dong) 41-3, Burim-ro 170beon-gil,Dongan-gu, Anyang-si, Gyeonggi-do, 14055 Republic of Korea
Contact Name:	Oh, Kevin / Regulatory Affairs Assistant Manager
Contact Number	+82-70-4466-3220
Registration Number:	3006013411, 3017585294
Name of Manufacturer:	Same as Sponsor

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

Trade Name:	VIVIX-M
Model Name:	FXMD-2430S, FXMD-1008S
Common Name:	Digital Mammography System
Classification Name:	Full Field Digital, System, X-Ray, Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1715
Product Code:	MUE
Device Class:	2

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

510(k) Number:	**K170930**
Applicant:	DRTECT Corporation
Trade Name:	RSM 2430C
Common Name:	Digital Mammography System
Classification Name:	Full Field Digital, System, X-Ray, Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892. 1715
Product Code:	MUE
Device Class:	2
Decision Date:	04/17/2017
Type:	Traditional

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

- General Description

VIVIX-M, a series of flat panel detectors models named; FXMD-2430S, FXMD-1008S, with imaging areas of 24cm x 30cm, 18cm x 24cm, respectively. The device intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo (a-SI)-detectors that create electrical signals. After the electrical signals are generated, it is converted to digital value, and the Software acquires and processes the data values from the detector. The resulting digital images will be displayed on monitors. These devices should be integrated with an operating PC and an X-Ray generator. It can be utilized to digitalize x-ray images and transfer for radiography diagnostic.
VXvue Mammo is a digital X-ray imaging software designed for mammography applications. It acquires, processes, and transmits digital images from VIVIX-M detectors (FXMD-1008S and FXMD-2430S) while ensuring compliance with DICOM standards for seamless integration with PACS and other medical systems.

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

VIVIX-M detectors are flat panel detectors used in mammographic applications to acquire digital images for screening and diagnosis.

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

Compared with the predicate, devices show the technological characteristics of the proposed VIVIX-M device to be substantially equivalent to the predicate device. The proposed devices are functionally identical to the predicate device.

8. Integrated System Requirements

Contents	Requirements
Tube Type	Rotating anode or Stationary
Target	Molybdenum, Rhodium or Tungsten
Bucky Size	18cm x 24cm or 24cm x 30cm
Grid	Moving
Filter	Mo, Rh
kVp	20 ~ 35 (Mo, W), 28 ~ 39 (Rh)
mAs	3 ~ 500

- Software Requirement
: These detectors are compatible with VXvue Mammo (V 1.0)

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

When compared to the predicate device (**K170930**), the VIVIX-M presented in this submission is substantially equivalent:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Communication Method
- Scintillator Materials
- Resolution

There is similar performance as follow.

- Performance (MTF)
- Performance (DQE)

There are no significant difference between the VIVIX-M and the predicate device that would adversely affect the use of the product. It is substantially equivalent to the predicate device in design, function, materials, operational principles and intended use.

Parameter	Predicate Device	Subject Device	Equivalence
510(k) Number	K170930	K241113	-
Manufacturer	DRTECH Corporation	Vieworks Co., Ltd.	-
Model Name	RSM 2430C	FXMD-2430S	-
Classification Name	Full Field Digital, System, X-ray, Mammographic		Equivalent
Classification Panel	Radiology		Equivalent
Classification Regulation	21 CFR 892.1715		Equivalent
Product Code	MUE		Equivalent
Device Class	2		Equivalent
Indications for Use	The RSM 2430C is a detector indicated for use in screening and diagnostic mammography.	VIVIX-M detectors are flat panel detectors used in mammographic applications to acquire digital images for screening and diagnosis.	Substantially Equivalent
Scintillating Material	Cesium Iodide	Thallium doped Cesium Iodide	Substantially Equivalent
Pixel Pitch (μm)	76	75	Substantially Equivalent
Pixel Matrix	3072x3840	3072×3840	Equivalent
Dimensions (H x W x D)	327.15mm x 253.75mm x 14.2mm	254.6 ㎜ × 327.6 ㎜ × 15.0 ㎜	Substantially Equivalent
Weight (kg)	1.5	FXMD-1008S: 1.0 FXMD-2430S: 1.2	-
Rated Power Supply	DC +12V	DC +24V, Max. 0.75A	-
Power Consumption	30W	Max. 18W	-
Data Output and Software Features	Rconsole 1	VXvue Mammo	-
MTF	70% at 2lp/mm 30% at 5lp/mm	54.9% at 3lp/mm 33.1% at 5lp/mm	Substantially Equivalent
DQE	43% at 2lp/mm 30% at 5lp/mm	59.0% at 3lp/mm 42.5% at 5lp/mm	Substantially Equivalent

Parameter	Predicate Device	Subject Device	Equivalence
510(k) Number	K170930	K241113	-
Manufacturer	DRTECH Corporation	Vieworks Co., Ltd.	-
Model Name	RSM 2430C	FXMD-1008S	-
Common Name	Digital Flat Panel X-ray Detector		Equivalent
Classification Name	Solid State X-Ray Imager (Flat Panel/Digital Imager)		Equivalent
Classification Panel	Radiology		Equivalent
Classification Regulation	21 CFR 892.1715		Equivalent
Product Code	MUE		Equivalent
Device Class	2		Equivalent
Indications for Use	The RSM 2430C is a detector indicated for use in screening and diagnostic mammography.	VIVIX-M detectors are flat panel detectors used in mammographic applications to acquire digital images for screening and diagnosis.	Substantially Equivalent
Scintillating Material	Cesium Iodide	Thallium doped Cesium Iodide	Substantially Equivalent
Pixel Pitch (μm)	76	75	Substantially Equivalent
Pixel Matrix	3072x3840	3072×2304	Substantially Equivalen
Dimensions (H x W x D)	327.15mm x 253.75mm x 14.2mm	254.6 ㎜ × 327.6 ㎜ × 15.0 ㎜	Substantially Equivalent
Weight (kg)	1.5	FXMD-1008S: 1.0 FXMD-2430S: 1.2	-
Rated Power Supply	DC +12V	DC +24V, Max. 0.75A	-
Data Output and Software Features	Rconsole 1	VXvue Mammo	-
MTF	70% at 2lp/mm 30% at 5lp/mm	52.7% at 3lp/mm 32.7% at 5lp/mm	Substantially Equivalent
DQE	43% at 2lp/mm 30% at 5lp/mm	65.8% at 3lp/mm 46.9% at 5lp/mm	Substantially Equivalent

10. Summary of Non-Clinical Data

This section provides a high-level summary of the non-clinical laboratory testing conducted to demonstrate substantial equivalence between the subject devices (VIVIX-M models FXMD-1008S and FXMD-2430S) and the predicate device (K170930). The testing complies with FDA-recognized standards and the recommendations outlined in the *Full Field Digital Mammography System - Class II Special Controls Guidance for Industry and FDA Staff* (March 27, 2012).

Testing Summary

The following non-clinical tests were performed to evaluate the performance of the subject devices:

1) **Modulation Transfer Function (MTF):**
   - Purpose: To assess spatial resolution.
   - Protocol: Conducted per IEC 62220-1-2:2007 standards using a tungsten edge phantom.
   - Results: Both models demonstrated spatial resolution equivalent to the predicate device, with MTF values exceeding specified thresholds.
2) **Detective Quantum Efficiency (DQE):**
   - Purpose: To evaluate signal-to-noise ratio transfer efficiency.
   - Protocol: Measurements followed IEC 62220-1-2:2007 guidelines using standard clinical exposure conditions.
   - Results: DQE values at all spatial frequencies were comparable to the predicate device, confirming equivalent imaging performance.
3) **Noise Power Spectrum (NPS):**
   - Purpose: To analyze noise characteristics.
   - Protocol: Conducted under seven exposure levels as per IEC 62220-1-2.
   - Results: NPS results confirmed consistent noise performance across tested exposure levels.
4) **Dynamic Range Testing:**
   - Purpose: To determine the range of exposure levels without saturation artifacts.
   - Protocol: Based on sensitometric response data from IEC 62220-1-2.
   - Results: Both models exhibited a wide dynamic range suitable for mammographic imaging.
5) **Image Erasure and Fading Test (Ghosting):**
   - Purpose: To assess residual image effects after repeated exposures.
   - Protocol: Evaluated using a Pb phantom under specified conditions.
   - Results: No significant ghosting or residual artifacts were observed.
6) **Automatic Exposure Control (AEC) Performance:**
   - Purpose: To verify compatibility with AEC systems for varying breast thicknesses.
   - Protocol: Tested across PMMA thicknesses from 20mm to 70mm in standard and magnification modes.
   - Results: AEC performance met manufacturer-defined limits, ensuring consistent image quality.
7) **Phantom Testing (ACR, TE, CDMAM Phantoms):**
   - Purpose: To evaluate image quality metrics such as detectability of specks, fibers, and masses.
   - Protocols:
     - ACR Phantom tested for visibility of structures under automatic exposure settings.
     - TE Phantom assessed line pair resolution and mass detection.
     - CDMAM Phantom analyzed contrast-detail thresholds.
   - Results: All tests demonstrated diagnostic image quality equivalent to or better than the predicate device.
8) **Patient Radiation Dose Measurement (Average Glandular Dose):**
   - Purpose: To ensure compliance with dose safety limits while maintaining image quality.
   - Protocol: Conducted under MQSA-compliant conditions simulating compressed breast thicknesses (30%, 50%, and 70% glandular tissue compositions).

- Results: Average glandular dose was within FDA-recommended limits for all scenarios.

Standards and Guidance Referenced

The following standards and guidance documents were utilized:

- IEC 62220-1-2:2007 (*Medical Electrical Equipment – Characteristics of Digital X-Ray Imaging Devices*).
- *Full Field Digital Mammography System – Class II Special Controls Guidance for Industry and FDA Staff*, March 27, 2012.
- MQSA requirements for average glandular dose limits.

Conclusion

The non-clinical testing results demonstrate that the VIVIX-M models FXMD-1008S and FXMD-2430S are substantially equivalent to the predicate device in terms of safety, effectiveness, and performance. The devices comply with applicable FDA-recognized consensus standards, ensuring suitability for their intended use in mammographic imaging.

11. Summary of Clinical Data

A clinical image evaluation according to CDRH's 'Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Full-Field Digital Mammography System' was conducted, and the study confirmed that the new x-ray detectors VIVIX-M provide images of equivalent diagnostic capability to the predicate device, RSM 2430C and its results demonstrate substantial equivalence.

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

The VIVIX-M Digital X-ray detectors are substantially equivalent to the currently marketed and predicate devices (K170930) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, Substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC60601-1, IEC 60601-1-2, and the clinical test, which complied with the requirements specified in the CDRH's 'Class II Special Controls Guidance Document: Full-Field Digital Mammography System'.

The results of these tests demonstrate that VIVIX-M Digital X-ray detectors meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performance is substantially equivalent to the predicate device as well.