November 15, 2024

Vieworks Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
115 Roosevelt, STE 200
IRVINE, CA 92620

Re: K241125
Trade/Device Name: Vivix-S 1751s
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: April 23, 2024
Received: April 23, 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,

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)*
K241125

Device Name
VIVIX-S 1751S

Indications for Use *(Describe)*
VIVIX-S 1751S series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S 1751S series is not intended for mammography 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

(K241125)

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

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

11/13/2024

**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, 431-060 Republic of Korea |
| Contact Name: | Oh, Kevin / 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: | VIVIX-S 1751S |
| Model Name: | FXRD-1751SA<br>FXRD-1751SB |
| Common Name: | Digital Flat Panel X-ray Detector |
| Classification Name: | Stationary X-ray system |
| Classification Panel: | Radiology |
| Classification Regulation: | 21 CFR 892.1680 |
| Product Code: | MQB |
| Device Class: | 2 |

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

| | |
|---|---|
| **510(k) Number:** | **K190611** |
| Trade Name: | VIVIX-S 1751S |
| Model Name: | FXRD-1751SB |
| Common Name: | Digital Flat Panel X-ray Detector |
| Classification Name: | Stationary X-ray system |
| Classification Panel: | Radiology |
| Classification Regulation: | 21 CFR 892.1680 |
| Product Code: | MQB |
| Device Class: | 2 |

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

- General Description

The VIVIX-S 1751S, available in models FXRD-1751SA and FXRD-1751SB, features a 17x51 inch imaging area. This device intercepts x-ray photons and uses a scintillator to emit visible spectrum photons. The FXRD-1751SA model uses a CsI:TI (Thallium doped Caesium Iodide) scintillator, while the FXRD-1751SB model uses a Gadox (Gadolinium Oxysulfide) scintillator. These photons illuminate an array of photo (a-SI) detectors, creating electrical signals. These signals are then converted to digital values, which are processed by software to produce digital images displayed on monitors.
The VIVIX-S 1751S must be integrated with an operating PC and an X-ray generator, and it can communicate with the generator via cable. It is designed for capturing and transferring digital x-ray images for radiography diagnosis. Note that the X-ray generator and imaging software are not included with the VIVIX-S 1751S.

**6. Intended Use [21 CFR 807.92(a)(5)]**

VIVIX-S 1751S series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S 1751S series is not intended for mammography applications.

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

Comparisons with the predicate, the subject device 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 device (K190611), the VIVIX-S 1751S (FXRD-1751SA and FXRD-1751SB) presented in this submission has the same:

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

There is similar performance as follows:

- Performance (MTF)
- Performance (DQE)

There are no significant differences between the subject device and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles, and intended use.

Comparison Table:

| Parameter | | Predicate Device | Subject Device | | Equivalence |
|---|---|---|---|---|---|
| 510(k) Number | | K190611 | K241125 | | - |
| Manufacturer | | Vieworks Co., Ltd. | | | - |
| Device Name | | VIVIX-S 1751S | VIVIX-S 1751S | | - |
| | Detector | FXRD-1751SB | FXRD-1751SA | FXRD-1751SB | - |
| | Scintillator | Gadox | CsI | Gadox | |
| | Power Supply Unit | FXRP-01A | FXRP-01A | FXRP-01A | Power Supply |
| | IO Box | - | - | - | Power Supply |
| | Software | - | - | - | Software |
| | MTF(Min) | 0.5 lp/mm: 81<br>1lp/mm: 56<br>2lp/mm: 22<br>3lp/mm: 9 | 0.5 lp/mm: 83<br>1lp/mm: 63<br>2lp/mm: 30<br>3lp/mm: 14 | 0.5 lp/mm: 81<br>1lp/mm: 56<br>2lp/mm: 22<br>3lp/mm: 9 | |
| | DQE(Min) | 0.5 lp/mm: 29<br>1lp/mm: 22<br>2lp/mm: 11<br>3lp/mm: 4 | 0.5 lp/mm: 38<br>1lp/mm: 33<br>2lp/mm: 23<br>3lp/mm: 14 | 0.5 lp/mm: 29<br>1lp/mm: 22<br>2lp/mm: 11<br>3lp/mm: 4 | |
| Common Name | | Digital Flat Panel X-ray Detector | | | Equivalent |
| Classification Name | | Stationary X-ray system | | | Equivalent |
| Classification Panel | | Radiology | | | Equivalent |
| Classification Regulation | | 21 CFR 892.1680 | | | Equivalent |
| Product Code | | MQB | | | Equivalent |
| Device Class | | 2 | | | Equivalent |
| Intended Use | | VIVIX-S 1751S series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S 1751S series is not intended for mammography applications. | VIVIX-S 1751S series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S 1751S series is not intended for mammography applications. | | Equivalent |

**9. Summary of Non-Clinical Data**

A comparison test was conducted between the subject device (VIVIX-S 1751S - FXRD-1751SA) and the predicate device (K190611) on the items such as DQE, MTF and spatial resolution. Both devices show similar performance results.

These detectors comply with the following international and FDA-recognized consensus standards:

- 21CFR1020.30, Diagnostic X-ray Systems and their major components
- 21CFR1020.31, Radiographic equipment
- - IEC 60601-1 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance.
- CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Equipment –Part 1 : General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)
- ANSI/AAMI ES60601-1 (2005+ C1:09+A2:10) (Medical Electrical Equipment – Part 1
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2 : General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

**10. Summary of Clinical Data**

A-Qualified Expert Evaluation study according to CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices was conducted, and the study confirmed that the VIVIX-S 1751S (FXRD-1751SA) provide images of equivalent diagnostic capability to the predicate device, the VIVIX-S 1751S (FXRD-1751SB), and its results demonstrate substantial equivalence.

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

The subject device is substantially equivalent to the currently marketed and predicate device (K190611) 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, 3 and the clinical test, which complied with the requirements specified in the CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

The results of these tests demonstrate that VIVIX-S 1751S Digital X-ray detectors meet 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 performs as well the predicate devices.

**12. FDA Guidance Documents Referenced**

Technical documents for FXRD-1751SA comply with the following FDA guidance documents.

- FDA Guidance on Submission of 510(k)s for Solid State X-ray Imaging Devices
- FDA Guidance on Pediatric Information for X-ray Imaging Device Premarket Notifications
- FDA Guidance on Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- FDA Guidance on Off-The-Shelf Software Use in Medical Devices