June 18, 2026

Vieworks Co., Ltd
℅ Juin Lee
Regulatory Affairs Specialist
Vieworks Co., Ltd.
41-3, Burim-Ro 170beon-Gil, Dongan-Gu, Anyang-Si,
GYEONGGI-DO, KOREA 14055

Re: K260820
Trade/Device Name: VIVIX-S 4386W(FXRD-4386WA)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: May 21, 2026
Received: May 21, 2026

Dear Juin Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

GABRIELA M. RODAL -S Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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)*
K260820

Device Name
VIVIX-S 4386W (FXRD-4386WA)

Indications for Use *(Describe)*
VIVIX-S 4386W is indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography. It is intended for both adult and pediatric populations.

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) #: K260820

510(k) Summary

Prepared on: 2026-05-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vieworks Co., Ltd.
Applicant Address	41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14055 Korea, Republic of
Applicant Contact Telephone	+827088764616
Applicant Contact	Ms. Juin Lee
Applicant Contact Email	jhlee@vieworks.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VIVIX-S 4386W (FXRD-4386WA)
Common Name	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name	Stationary x-ray system
Regulation Number	892.1680
Product Code(s)	MQB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220239	VIVIX-S 4386W	MQB

Device Description Summary

21 CFR 807.92(a)(4)

VIVIX-S 4386W, a flat panel detector model named; FXRD-4386WA with imaging areas of 43cm x 86cm. 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 which 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

VIVIX-S 4386W is indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography. It is intended for both adult and pediatric populations.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The modification made on the subject device(Model Name: FXRD-4386WA) has no effect on the indications for use, therefore the indications for use remain same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device incorporates a modified scintillator (GadOx to CsI)compared to the predicate device, representing a change in technological characteristics. As a result, differences are observed in key imaging performance parameters, including DQE and MTF.

However, the subject device employs the same fundamental imaging principles and detector architecture as the predicate device. Performance evaluation demonstrates that DQE and MTF remain comparable and within acceptable ranges for the intended use, and these differences do not raise new questions of safety or effectiveness.
Therefore, the subject device is considered substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical performance testing was conducted to compare the subject device with the predicate device. Imaging performance parameters, including modulation transfer function (MTF) and detective quantum efficiency (DQE), were evaluated. The subject device demonstrated slightly higher values under the specified test conditions, indicating performance comparable to or better than the predicate device.

Electrical safety and electromagnetic compatibility (EMC) testing were conducted in accordance with IEC 60601-1 and IEC 60601-1-2, and all applicable requirements were met.

In summary, the subject device, FXRD-4386WA, has the same indications for use and similar technological characteristics as the predicate device and does not raise any new questions of safety or effectiveness. Therefore, the device is substantially equivalent to the predicate device.