November 8, 2021

FUJIFILM Corporation
% Mr. Jeffrey Wan
Manager, Regulatory Affairs
FUJIFILM Medical Systems U.S.A, Inc.
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

Re: K212956
Trade/Device Name: FDR CROSS (DR-XD 3000)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: September 14, 2021
Received: September 16, 2021

Dear Mr. Wan:

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 (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 located 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.

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

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

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212956

Device Name
FDR CROSS (DR-XD 3000)

Indications for Use *(Describe)*

The DR-XD 3000 is a mobile C-arm system with detachable flat panel detector, which is intended for use in providing medical imaging for general populations including pediatrics. The device provides pulsed fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures and digital radiographic imaging. It is intended for use in procedures such as cholangiography, endoscopic, urologic, orthopedic, neurologic, peripheral vascular, critical care, emergency room procedures. This device does not support cardiac procedures and is not intended for use in performing 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.

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510(k) Summary
K212956

FDR CROSS (DR-XD 3000)

Date: August 23, 2021

Submitter's Information:

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi, Ashigarakammi-Gun, Kanagawa, Japan

Contact Person:

Name: Jeffrey Wan
Title: Manager, Regulatory Affairs
Telephone: (201) 675-8947
E-Mail: Jeffrey.wan@fujifilm.com

Identification of the Device:

Proprietary/Trade Name:	FDR CROSS (DR-XD 3000)
Classification Name:	Image-intensified fluoroscopic x-ray system
Regulations Number:	21 CFR 892.1650
Product Codes:	OWB, JAA
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Interventional Fluoroscopic X-Ray System

Identification of the Legally Marketed Device:

1.Ziehm Vision FD, K193230 cleared 12/20/2019

Classification Name:	Image-intensified fluoroscopic x-ray system
Regulations Number:	21 CFR 892.1650
Product Codes:	OWB, JAA
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Interventional Fluoroscopic X-Ray System

2. FDR D-EVO III Flat Panel Detector System, K192932 cleared 11/12/2019

Classification Name:	Stationary x-ray system
Regulations Number:	21 CFR 892.1680
Product Codes:	MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)

I. DEVICE DESCRIPTION

The FDR CROSS is mobile X-ray fluoroscopy equipment designed and manufactured by Fujifilm Corporation (FTYO) featuring high mobility arising from small size and light

weight. The C-arm cart irradiates X-rays and detects X-rays by the flat panel sensor to perform X-ray fluoroscopy and radiography. A flat panel sensor has higher sensitivity than an image intensifier, which can result in dose reduction.
The flat panel sensor is same as FDR D-EVO III Flat Panel Detector System (predicate device) cleared as radiography purpose. (K192932)
The system contains the console software (DR-ID 340CL), control cabinet software (DR-ID 3000MC) and X-ray controller software (DR-ID 3000SX). The DR-ID 340CL and DR-ID 3000MC is modified to add fluoroscopic function based on the DR-ID 300CL and DR-ID 1200MC which are used in FDR D-EVO III Flat Panel Detector System cleared as radiography purpose (K192932). The software's Level of Concern is Moderate.

II. INDICATIONS FOR USE

The DR-XD 3000 is a mobile C-arm system with detachable flat panel detector, which is intended for use in providing medical imaging for general populations including pediatrics. The device provides pulsed fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures and digital radiographic imaging. It is intended for use in procedures such as cholangiography, endoscopic, urologic, orthopedic, neurologic, peripheral vascular, critical care, emergency room procedures. This device does not support cardiac procedures and is not intended for use in performing mammography.

III. SUBSTANTIAL EQUIVALENCE

The FDR CROSS (DR-XD 3000) is substantially equivalent to the following legally marketed device.

Legally Marketed Device	510(k) #	Clearance Date
Ziehm Vision FD	K193230	20/12/2019

Both systems, the subject device and the predicate (K193230), are intended for use in providing medical imaging for general populations. The device provides pulsed fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures.
The Indications for Use of the subject device are almost identical to the predicate device and representing identical indications for use and type of interventional and fluoroscopic procedures.
The indications for use for of subject device are includes the statement that it has "detachable flat panel sensor" and "digital radiographic imaging". Further it includes the statement that it does not support cardiac procedures. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.
The key technological characteristics of the subject device and the predicate device are similar, and therefore the differences described below do not affect the Indications for Use.

	Subject Device FDR CROSS (DR-XD 3000)	**Predicate Device K193230 Dec,20,2019 Ziehm Vision FD**
X-ray Generator		
Maximum Parameter	max. 2.0 kW, max. 110 kV, max. **25 mA**	max. 2.0 kW, max. 110 kV, max. 20 mA
Pulsed Fluoroscopy:	kV range: 40 - 110 kV mA range: **0.8 - 20 mA**	kV range: 40 - 110 kV mA range: 0.2 - 16 mA

Operating values		
Pulsed Fluoroscopy: Pulse and Duration	・pulse width: **18 - 60 ms** ・pulse rate: 1, 2, **4, 8**, 15 pulse/s	・pulse width: 10 - 40 ms (8” FPD Varex aSi) ・pulse rate: 1, 2, 5, 10, 15, 30 pulse/s
Digital Radiography / Operating Values	(Snapshot) kV range: 40 - 110 kV mA range: up to 20 mA **(Radiography)** **kV range: 40 - 110 kV** **mA range: up to 25 mA** **mAs range: 0.25 - 25 mAs**	(Snapshot) kV range: 40 - 110 kV mA range: up to 20 mA
Image Detector		
Detector Sizes	**・Detachable Flat Panel Sensor holder** **・Detachable Flat Panel sensor** **・Size:** **(Fluoroscopy/Radiography)** **247.2 mm x 297 mm** **(DR-ID 1814SE)** **350.4 mm x 425.4 mm** **(DR-ID 1811SE)** **424.8 mm x 425.4 mm** **(DR-ID 1812SE)** **(Radiography Only)** **350.4 mm x 425.4 mm** **(DR-ID 1831SE)** **424.8 mm x 425.4 mm** **(DR-ID 1832SE)**	Size: 19.9 cm x 19.9 cm
Electrical Requirements		
Electrical Requirements	• Power supply: 100-240 VAC (± 10%), 50/60 Hz **Battery (Li-ion)** • Current consumption: **100 V: 12 A** **240 V: 5 A** • Max. impedance: **≤ 0.2 Ω** • Class I equipment (when operated by connecting the power cable), **Internally powered equipment (when operated with the battery)**, Type B	• Power supply: 100-240 VAC (± 10%), 50/60 Hz • Current consumption: 100-120 V: 10 A continuous, 22 A short time 200-240 V: 8 A continuous, 16 A short time • Max. impedance: 100-200 V: ≤ 0.3 Ω 220-240 V: ≤ 0.6 Ω • Class I equipment, Type B
Mechanics		
Weight	C-arm Cart: max. **249kg**	Mobile Stand: max. 337kg

	Monitor Cart: max. **50kg**	Monitor Cart: max. 233kg
Digital Image Processing		
Real-Time processing functions	• Recursive filter: 4 levels **• Noise reduction filter(FNC2)** • Edge enhancement filter(MFP2): **4 levels** • Windowing • Digital image rotation and reversal without radiation • Grayscale inversion • Virtual collimators	• Recursive filter: 4 levels • Edge enhancement filter: 5 levels • Windowing and step windowing • Digital image rotation and reversal without radiation • Grayscale inversion • Virtual collimators
Post-Processing Functions	(Fluoroscopy) • Zoom: 1 level • Windowing **(Radiography)** **• Zoom** **• Windowing** **• Gradation conversion(GP)** **• Standardization (EDR)** **• Image enhancement (frequency processing(RP), dynamic range compression(DRC), multi frequency processing(MFP))** **• Noise suppression (Granular noise suppression(FNC2), Grid moire removal(GPR), scattered X-ray reduction(virtual grid))**	Edge enhancement: 5 levels • Zoom: 3 levels • Image rotation • Windowing and step windowing • Grayscale inversion • Image cropping (digital collimators) • Digital measurement functions: distance/angle (option)

The virtual grid function is the same as K153464.

IV. SUMMARY OF STUDIES

Non-clinical Performance Data: The FDR CROSS (DR-XD 3000) conforms to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 62304, IEC 62366-1, DICOM 3.0, IEC 60601-2-43, IEC 60601-2-54. In addition, the FDA's *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices* (issued on August 6, 1999) was followed to describe the detector characteristics, and *Radio Frequency Wireless Technology in Medical Devices* (issued August 14, 2013) was followed to test. As required by the risk analysis, necessary verification and validation activities were performed including software testing, and the results were satisfactory.

V. CONCLUSION

Based upon the supporting data summarized above, we concluded the FDR CROSS (DR-XD 3000) is as safe and effective as the legally marketed device Ziehm Vision FD (K193230) and does not raise different questions of safety and effectiveness than Ziehm Vision FD (K193230).