FUJIFILM Corporation
% Mrs. Kamila Sak
Regulatory Affairs Specialist
FUJIFILM Medical Systems U.S.A, Inc.
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

April 10, 2020

Re: K200668
Trade/Device Name: DR-ID 1200SDK System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: March 12, 2020
Received: March 13, 2020

Dear Mrs. Kamila Sak:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200668

Device Name
DR-ID 1200SDK System

Indications for Use *(Describe)*
The Wireless/Wired DR-ID 1200SDK System is intended to capture for display radiographic images of human anatomy . It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The DR-ID 1200SDK System is not intended for mammography, fluoroscopy, tomography, and angiography 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.

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510(k) Summary

K200668

Date Prepared: April 02, 2020

Submitter's Information:

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan
FDA Establishment Registration Number: 3001722928

Contact Person:

Kamila Sak
Specialist, Regulatory Affairs
Telephone: (347) 577-2309
Email: kamila.sak@fujifilm.com

Device Name and Classification:

Product Name:	DR-ID 1200SDK System
Model Number:	DR-ID 1200
Regulation Description:	Stationary x-ray system
Regulation Medical Specialty:	Radiology
CFR Section:	21 CFR 892.1680
Device Class:	Class II
Product Code:	MQB

Predicate Device:

Product Name:	FDR D-EVO II Flat Panel Detector System
Model Number:	DR-ID 1200
Regulation Description:	Stationary x-ray system
Regulation Medical Specialty:	Radiology
CFR Section:	21 CFR 892.1680
Device Class:	Class II
Product Code:	MQB

The subject device DR-ID 1200SDK System is a variation of the legally marketed FDR D-EVO II Flat Panel Detector System (DR-ID 1200). The predicate device FDR D-EVO II had received 510(k) clearance via K142003 on October 21, 2014, and was documented internally several times after that.

Indications for Use:

The Wireless/Wired DR-ID 1200SDK System is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The DR-ID 1200SDK System is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Description of the Device:

The subject device DR-ID 1200SDK is a detector/software system, previously cleared as a component of the predicate FDR D-EVO II (K142003). The x-ray generator, necessary for a fully-operational radiographic system, is not part of the subject device. The device is designed as an alternative system added in FDR D-EVO II Flat Panel Detector System (DR-ID 1200) made by FUJIFILM. The subject device does not include imaging processing unit FDX Console (DR-ID 300CL) but the function of console is combined by system integrators. Both the subject device and predicate device are indicated for general purpose radiography. The software package is unchanged from the predicate, however the SW name was changed from DR-ID 1200MC (K142003) to DR-ID 1200SDK.

Performance Data:

Non-clinical Performance Data: DR-ID 1200SDK conforms to the following standards: AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 62304 and IEC 62366-1. In addition, the FDA's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices (September 1, 2016) was followed to describe the detector characteristics.

As required by the risk analysis, necessary verification and validation activities were performed including software testing, and the results were satisfactory.

Clinical Performance Data: No clinical study has been performed. The substantial equivalence has been demonstrated by non-clinical studies.

Comparison of Technological Characteristics:

The proposed device DR-ID 1200SDK differs from the predicate device in the following minor modifications:

- Removal of imaging processing unit FDX Console (DR-ID 300CL), optional Docking Stand (DR-ID 1200DS), and optional Fujifilm Access Point
- Removal of memory exposure mode

Substantial Equivalence:

The company's DR-ID 1200SDK System (DR-ID 1200) has the same intended use and indications for use as the previously cleared predicate D-EVO II Flat Panel Detector System (DR-ID 1200) cleared under K142003. The differences described below do not affect the indications for use, the fundamental scientific technology, safety and effectiveness, and image

quality.

The subject device DR-ID 1200SDK system does not include imaging processing unit FDX Console (DR-ID 300CL), Docking stand, and Fujifilm access point. Docking stand and Fujifilm access point are optional components and do not affect the Indications for Use. DR-ID 1200SDK system can be connected to the console made by system integrators. The DR-ID 1200SDK system itself does not have a user interface, but when combined with console, it has almost the same functions and performance as the predicate device.

The subject device DR-ID 1200SDK system does not support the memory exposure mode. The memory exposure mode is a function for capturing an image with the flat panel detector alone without image processing unit, storing the image in the flat panel detector memory, and transmitting the image to the image processing unit later. Even if this function is not supported, images can be sent to the image processing unit; thus the change does not affect the indications for use.

Therefore, the subject device DR-ID 1200SDK System (DR-ID 1200) can be considered to be substantially equivalent to the predicate device FDR D-EVO II Flat Panel Detector System (DR-ID 1200).

Comparison of Technological Characteristics:

A comparison of the technological characteristics between the subject device and predicate device is provided below:

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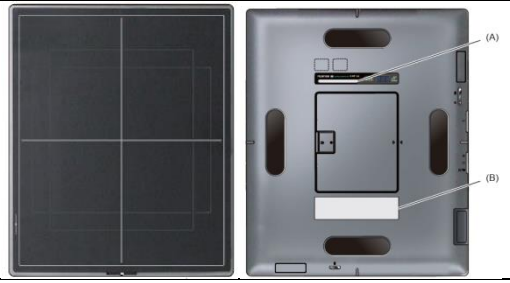
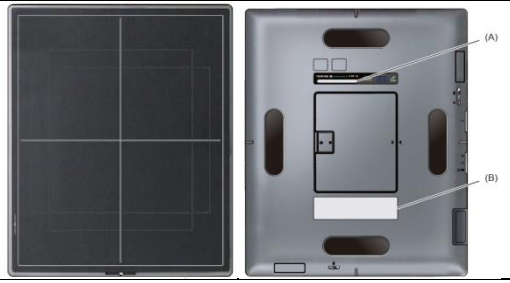
	Subject Device DR-ID 1200SDK system	Predicate Device K142003, cleared Oct. 21, 2014 FDR D-EVO II	Comment for safety and performance
Indications for Use	The Wireless/Wired DR-ID 1200SDK system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The DR-ID 1200SDK System is not intended for mammography, fluoroscopy, tomography, and angiography applications.	The Wireless/Wired FDR D-EVO II flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO II is not intended for mammography, fluoroscopy, tomography, and angiography applications.	Same as the predicate device except the device name
Detector Characteristics			
Appearance			Same
Scintillator	DR-ID1201SE, DR-ID1202SE Gd_2O_2S:Tb (GOS) DR-ID1211SE, DR-ID1212SE, DR-ID1213SE CsI:Tl (CsI)	DR-ID1201SE, DR-ID1202SE Gd_2O_2S:Tb (GOS) DR-ID1211SE, DR-ID1212SE, DR-ID1213SE CsI:Tl (CsI)	Same
X-ray Conversion	Indirect conversion (a-Si)	Indirect conversion (a-Si)	Same
Unique Detector Characteristic	ISS (irradiation side sampling): captures image from front of detector, reducing blur, resulting in an increase in sharpness and DQE	ISS (irradiation side sampling): captures image from front of detector, reducing blur, resulting in an increase in sharpness and DQE	Same
Detector Cord	Wired / Wireless	Wired / Wireless	Same
Detector Weight (with battery)	DR-ID1201SE : Approx.5.7 lbs (2.5kg) DR-ID1211SE : Approx.5.8 lbs (2.6kg) DR-ID1202SE, DR-ID1212SE : Approx.7.1 lbs (3.2kg) DR-ID1213SE : Approx.3.3 lbs (1.5kg)	DR-ID1201SE : Approx.5.7 lbs (2.5kg) DR-ID1211SE : Approx.5.8 lbs (2.6kg) DR-ID1202SE, DR-ID1212SE : Approx.7.1 lbs (3.2kg) DR-ID1213SE : Approx.3.3 lbs (1.5kg)	Same
Withstand Load	Point load: 1600N (160kg or 352.7 lbs) / ø40mm (1.6in.) Surface load: 3100N (310kg or 683.4 lbs)	Point load: 1600N (160kg or 352.7 lbs) / ø40mm (1.6in.) Surface load: 3100N (310kg or 683.4 lbs)	Same

CR/DR Integration	N/A	FDX Workstation capable of simultaneous connection to Fujifilm CR and FDR D-EVO II	FDX Workstation is not included in the subject device.
Exposure size/Active Area (inch)	DR-ID1201SE, DR-ID1211SE :13.8x16.8 DR-ID1202SE, DR-ID1212SE :16.7x16.8 DR-ID1213SE : 9.07x11.3	DR-ID1201SE, DR-ID1211SE :13.8x16.8 DR-ID1202SE, DR-ID1212SE :16.7x16.8 DR-ID1213SE : 9.07x11.3	Same
Exposure size/Active Area (cm)	DR-ID1201SE, DR-ID1211SE :35.04x42.54 DR-ID1202SE, DR-ID1212SE :42.48x35.05 DR-ID1213SE : 23.04x28.80	DR-ID1201SE, DR-ID1211SE :35.04x42.54 DR-ID1202SE, DR-ID1212SE :42.48x35.05 DR-ID1213SE : 23.04x28.80	Same
Number of Pixels	DR-ID1201SE, DR-ID1211SE :2336x2836 DR-ID1202SE, DR-ID1212SE :2832x2836 DR-ID1213SE : 1536x1920	DR-ID1201SE, DR-ID1211SE :2336x2836 DR-ID1202SE, DR-ID1212SE :2832x2836 DR-ID1213SE : 1536x1920	Same
Dimensions (Detector exterior)	DR-ID1201SE, DR-ID1211SE : 38.4cm(W) x 46.0cm(D) x 1.5cm(H) DR-ID1202SE, DR-ID1212SE : 46.0cm(W) x 46.0cm(D) x 1.5cm(H) DR-ID1213SE : 26.8cm(W) x 32.8cm(D) x 1.5cm(H)	DR-ID1201SE, DR-ID1211SE : 38.4cm(W) x 46.0cm(D) x 1.5cm(H) DR-ID1202SE, DR-ID1212SE : 46.0cm(W) x 46.0cm(D) x 1.5cm(H) DR-ID1213SE : 26.8cm(W) x 32.8cm(D) x 1.5cm(H)	Same
Pixel Size	150 µm	150 µm	Same
Acquisition Bit Depth	16 bit	16 bit	Same
DQE (RQA5, 1 lp/mm) – detector alone, without tabletop	DR-ID1201SE,DR-ID1202SE 31% Measurement tolerance (±10%) DR-ID1211SE,DR-ID1212SE,DR-ID1213SE 54% Measurement tolerance (±10%)	DR-ID1201SE,DR-ID1202SE 31% Measurement tolerance (±10%) DR-ID1211SE,DR-ID1212SE,DR-ID1213SE 54% Measurement tolerance (±10%)	Same
MTF (RQA5, 2 lp/mm)	DR-ID1201SE,DR-ID1202SE 42%(High mode) Measurement tolerance (±10%) DR-ID1211SE,DR-ID1212SE,DR-ID1213SE 54%(High mode) Measurement tolerance (±10%)	DR-ID1201SE,DR-ID1202SE 42%(High mode) Measurement tolerance (±10%) DR-ID1211SE,DR-ID1212SE,DR-ID1213SE 54%(High mode) Measurement tolerance (±10%)	Same
Detector tiling	One tile	One tile	Same
Method of Detector Cooling	No special cooling required	No special cooling required	Same
Operating Temperature (˚C)	15 to 30˚C (operating condition) 5 to 35˚C (non-operating condition)	15 to 30˚C (operating condition) 5 to 35˚C (non-operating condition)	Same
Auto X-ray	Supported	Supported	Same

Detection Feature			
Wireless Feature			
Wireless Specifications	IEEE802.11n (2.4GHz, 5.2GHz, 5.3GHz, 5.6GHz, 5.8GHz)	IEEE802.11n (2.4GHz, 5.2GHz, 5.3GHz, 5.6GHz, 5.8GHz)	Same
Security feature	MAC Address Filtering (unique IP address) Wireless LAN Segmentation WPA2-PSK encryption with AES (Advanced Encryption Standard)	MAC Address Filtering (unique IP address) Wireless LAN Segmentation WPA2-PSK encryption with AES (Advanced Encryption Standard)	Same
Recommended Wireless Access Point	D-Link DAP-2695 Silex SX-AP-4800AN2	D-Link DAP-2695 Silex SX-AP-4800AN2 Fujifilm AP (853Y120009)	Not related since Fujifilm AP is mobile-dedicated
Battery Specifications	~ 500 exposures or 3 hours Standby time: ~ 4 hours (max 18 hours with extra sleep mode*) Charging time: ~ 3 hours	~ 500 exposures or 3 hours Standby time: ~ 4 hours (max 18 hours with extra sleep mode*) Charging time: ~ 3 hours	Same
Additional Components for Wireless feature	Wireless Access Point (WAP) Battery Charger Li-ion Battery	Wireless Access Point (WAP) Battery Charger Li-ion Battery	Same
Others			
Memory storage function	**No**	Yes	Not related (refer to 12.2.3)
Waterproof level	IPX6: Protected against powerful water jets	IPX6: Protected against powerful water jets	Same
Antimicrobial coating	Ag (silver)-based HYDRO AG coating technology	Ag (silver)-based HYDRO AG coating technology	Same
Image compression	Yes	Yes	Same
System Components			
Grids (Optional)	Custom fit grids (wired) Standard grids (wireless)	Custom fit grids (wired) Standard grids (wireless)	Same
Standard Configuration Components	System requires one or more DR-ID12xxSE detectors, one or two power supply unit(s), one or two or three power box(es) and one control software*. *The control software is installed in the Console PC.	System requires one FDX Console, one or more DR-ID12xxSE detectors, one or two power supply unit(s), one or two or three docking stand(s), one or two or three power box(es) and one control unit*. *Depending on configuration, the control unit software can be installed in the FDX Console PC.	Substantially equivalent except for FDX Console. The whole system including the Console is specified by system

			integrators.
Workstation	N/A	FDX Console Version 8.0 and above	The system including the Console is specified by the system integrators.
Minimum Basic Computer Configuration	CPU: Core 2 Duo or later (Performance equivalent or more),Windows 10, Bus: PCI, RAM: 4GB, Hard Drive: 80 GByte	Computer “Off the Shelf” consisting of: Mini Tower, CPU: Core 2 Duo or later (Performance equivalent or more), Windows 7, Bus: PCI, RAM: 4GB, Hard Drive: 80 GByte, Keyboard, Mouse, Barcode scanner, DVD Drive, 17 “ or 21” color (touchscreen optional) Monitor.	The PC of the system is specified by system integrators.
Image Processing	N/A	EDR, GP, RP, MFP, DRC, FNC,DVII,VG	The image processing is specified by system integrators.
Operating System	Control software (DR-ID1200SDK): Windows 10 *32bit or 64bit SP1	FDX Console: Windows 7*/10 *32bit or 64bit SP1 Power supply unit (DR-ID1200MP): WindRiverLinux2.0 (kernel:2.6.21.7) Control cabinet (DR-ID1200MC)*: Windows Vista and Windows 7 *Control cabinet may not be needed depending on configuration.	The operating system of Console is specified by system integrators.
Image Transfer	N/A	Standard network connectivity via DICOM protocol & via Fuji DMS Network	Standard network connectivity is specified by system integrators.

Conclusion:

This Special 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate device.