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

November 12, 2019

Re: K192932
Trade/Device Name: FDR D-EVO III flat panel detector system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 16, 2019
Received: October 17, 2019

Dear Ms. 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)*
K192932

Device Name
FDR D-EVO III flat panel detector system

Indications for Use *(Describe)*
The Wireless/Wired FDR D-EVO III 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 III 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

K192932

Date Prepared: November 05, 2019

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
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Device Name and Classification:

Product Name:	FUJIFILM FDR D-EVO III Flat Panel Detector System
Model Number:	DR-ID 1800
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR 892.1680
Device Class:	Class II
Product Code:	MQB

Predicate Device:

Product Name	FUJIFILM FDR D-EVO II Flat Panel Detector System (DR-ID 1200)
510(k) Number	K142003
Classification Name	Stationary x-ray system
Classification Panel	Radiology
CFR Section	21 CFR 892.1680
Device Class	Class II
Product Code	MQB

The subject device FDR D-EVO III Flat Panel Detector System (DR-ID1800) is essentially a modified version of legally marketed FDR D-EVO II Flat Panel Detector System (DR-

ID1200). The predicate device DR-ID 1200 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 FDR D-EVO III 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 III is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Description of the Device:

The subject device FDR D-EVO III Flat Panel Detector System (DR-ID1800) is a portable digital detector system that interfaces with, and acquires and digitizes x-ray exposures from, standard radiographic systems. DR-ID1800 is designed to be used in any environment that would typically use a radiographic cassette for examinations of adults, pediatrics and neonates. The detector models support both wireless and wired/tethered data communication between the detector and the system. Detectors can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid or free cassette exams. The software that supports the functions of the FDR D-EVO III Flat Panel Detector System is unchanged from the predicate device, cleared under K142003.

Comparison of Technological Characteristics:

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

Comparison Item	Subject Device FDR D-EVO III FPD system (DR-ID1800)	Predicate Device FDR D-EVO II FPD system (DR-ID 1200)	Discussion & Conclusion
Indications for Use	The Wireless/Wired FDR D-EVO III 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 III 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(Except device name)
Detector characteristics			
Panel variation	DR-ID 1801SE (14" x 17") DR-ID 1802SE (17" x 17")	DR-ID 1201SE (14" x 17"),DR-ID 1202SE (17" x 17") DR-ID 1211SE (14" x 17"),DR-ID 1212SE (17" x 17") DR-ID 1213SE (9" x 11")	Described as below
Scintillator	GOS (Gadolinium oxysulfide)	GOS (Gadolinium oxysulfide); - DR-ID 1201SE (14" x 17") - DR-ID 1202SE (17" x 17") CsI(Secium Iodide); - DR-ID 1211SE (14" x 17") - DR-ID 1212SE (17" x 17") - DR-ID 1213SE (9" x 11")	The subject device has only GOS based detector. No impact on safety or effectiveness of the device.
Dimensions (Detector exterior)	DR-ID1801SE : 38.4 cm x 46 cm x 1.5 cm DR-ID1802SE : 46 cm x 46 cm x 1.5 cm	DR-ID1201SE, DR-ID1211SE : 38.4 cm x 46 cm x 1.5 cm DR-ID1202SE, DR-ID1212SE : 46 cm x 46 cm x 1.5 cm DR-ID1213SE : 26.8 cm x 32.8 cm x 1.5 cm	Same*
Number of Pixels	DR-ID1801SE: 2336 x 2836 DR-ID1802SE: 2832 x 2836	DR-ID1201SE, DR-ID1211SE : 2336 x 2836 DR-ID1202SE, DR-ID1212SE : 2832 x 2836 DR-ID1213SE :1920 x 1536	Same*
Pixel Size	150 µm	150 µm	Same

Comparison Item	Subject Device FDR D-EVO III FPD system (DR-ID1800)	Predicate Device FDR D-EVO II FPD system (DR-ID 1200)	Discussion & Conclusion
X-ray Conversion	Indirect conversion (a-Si)	Indirect conversion (a-Si)	Same
TFT sensor substrate	Film-based TFT substrate	Glass-based TFT substrate	Only the material of substrate is changed, there is no change in the mechanism. No impact on safety or effectiveness of the device.
DQE (RQA5, 1 lp/mm, 1mR) – detector alone, without tabletop	33% Measurement tolerance (±10%)	31% Measurement tolerance (±10%)	Slightly improved DQE by using Film-based TFT substrate This difference of DQE does not impact clinical Image Quality.
MTF (RQA5, 1 lp/mm)	Two options are available by setting. -Normal 60% -High 75%	Two options are available by setting. -Normal 60% -High 75%	Same
Appearance characteristics	- Adopt more rounded shape - Changed alighnment of LEDs/Operation button that is easier to use	- Rounded corners and curved edges are adopted. - LEDs/Operation button is placed.	This difference of detector appearance does not impact on safety or effectiveness of the device.
Detector Weight	DR-ID1801SE: : Approx. 1.8kg (without battery) DR-ID1802SE : Approx. 2.1kg (without battery)	DR-ID1201SE : Approx. 2.3kg (without battery) DR-ID1202SE : Approx. 2.9kg (without battery) DR-ID1211SE : Approx. 2.4kg (without battery) DR-ID1212SE : Approx. 3.0kg (without battery) DR-ID1213SE : Approx. 1.3kg (without battery)	This difference of detector weight does not impact on safety or effectiveness of the device.

Comparison Item	Subject Device FDR D-EVO III FPD system (DR-ID1800)	Predicate Device FDR D-EVO II FPD system (DR-ID 1200)	Discussion & Conclusion
Software Charactisctic			
Workstation	FDX Console Version 13.0	FDX Console Version 8.0 and above (Latest version: 12.1)	This difference of the workstation is only to add this subject detector as the connectable Flat panel detector options. No impact on safety or effectiveness of the device.

*Note: CsI scintillator has not been adopted in DR-ID 1800 yet. Then, we discuss and conclude the substantial equivalence by excluding CsI scintillator.

Substantial Equivalence:

Both the subject device and predicate device have the same Indication for Use. There are some differences, but the differences are minor and do not affect fundamental scientific technology, principles of operation, safety and effectiveness, and image quality. Therefore, the subject device FDR D-EVO III Flat Panel Detector System (DR-ID1800) can be considered to be substantially equivalent to the predicate device FDR D-EVO II Flat Panel Detector System (DR-ID1200) limited to the flat panel detector with GOS scintillator.

Summary Of Studies:

Non-clinical Performance Data: FDR D-EVO III Flat Panel Detector System (DR-ID1800) conforms to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 62304, IEC 62366-1, IEC 62494-1 and DICOM. 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, and Radio Frequency Wireless Technology in Medical Devices (August 14, 2013) was followed to test wireless features. As required by the risk analysis, necessary verification and validation activities were performed including software testing, and the results were satisfactory. Furthermore, the image quality evaluation confirmed that the image quality of the FDR D-EVO III Flat Panel Detector System (DR-ID1800) is substantially equivalent to that of the predicate device.

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

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.