November 1, 2019

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

Re: K192440
Trade/Device Name: FDR SE Lite Flat Panel Detector System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: September 5, 2019
Received: September 6, 2019

Dear 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,

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)*

K192440

Device Name
FDR SE Lite Flat Panel Detector System

Indications for Use *(Describe)*
The FDR SE Lite 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 wherever conventional film/screen or CR systems may be used. The FDR SE Lite is not intended for mammography, fluoroscopy, tomography, and angiography applications, as well as pediatric and neonatal exams.

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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FUJIFILM
Fujifilm Medical Systems, USA

510(k) Summary

FDR SE-Lite Flat Panel Detector System (DR-ID 330)

Date: September 5, 2019

Submitter's Information:

FUJIFILM Corporation

798 Miyanodai Kaisei-Machi

Ashigarakami-Gun, Kanagawa, 258-8538, Japan

FDA Establishment Registration Number: 3001722928

Contact Person:

Name:	Kamila Sak
Title:	Specialist, Regulatory Affairs
Telephone:	(347) 577-2309

Identification of the Device:

Proprietary:	FDR SE Lite Flat Panel Detector System
Model Number:	DR-ID330
Classification Name:	Stationary X-ray system
CFR Section:	21 CFR 892.1680
Product Codes:	90 MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector System

Identification of the Legally Marketed Device:

FDR D-EVO II Flat Panel Detector System (DR-ID 1200), K142003 cleared 10/21/2014

I. DEVICE DESCRIPTION

Fujifilm's FDR SE Lite (DR-ID 330), is a portable digital detector system that interfaces with, and acquires and digitizes X-ray exposures from, standard radiographic systems. DR-ID 330 is designed to be used in any environment that would typically use a radiographic cassette for examinations of adults, not for pediatrics and neonates. The detector models support only wireless data communication between the detector and the console. 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.

II. INDICATIONS FOR USE

The FDR SE Lite 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 wherever conventional film/screen or CR systems may be used. The FDR SE Lite is not intended for mammography, fluoroscopy, tomography, and angiography applications, as well as pediatric and neonatal exams.

III. SUBSTANTIAL EQUIVALENCE

Fujifilm FDR SE Lite FPD System (DR-ID 330) is substantially equivalent to the following legally marketed device.

Legally Marketed Device	510(k) #	Clearance Date
FDR D-EVO II Flat Panel Detector System (DR-ID1200)	K142003	10/21/2014

Both the subject device FDR SE Lite (DR-ID 330) and predicate device FDR D-EVO II (DR-ID 1200) in K142003 are portable digital detector systems that are intended to be used for the same purposes except for pediatric and neonatal use and wired communication. The most detector characteristics remain unchanged for FDR SE Lite, and the image quality is substantially equivalent to the predicate device. The design made for the FDR SE Lite have been successfully tested and validated as summarized below.

IV. SUMMARY OF STUDIES

Non-clinical Performance Data: FDR SE Lite FPD System (DR-ID330) conforms to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 62366 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 SE Lite system using MarsXF detectors 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.

V. CONCLUSION

Based upon the supporting data summarized above, we concluded FDR SE Lite Flat Panel Detector System (DR-ID 330) is as safe and effective as the legally marketed device DR-ID 1200 (K142003), and do not raise different questions of safety and effectiveness than K142003.