DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2014

Fujifilm Medical Systems U.S.A., Inc.
% Ms. Katherine Y. Choi
Regulatory Affairs Lead
419 West Avenue
STAMFORD CT 06902

Re: K141765
Trade/Device Name: FDR D-EVO Flat Panel Detector System (DR-ID600)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 2, 2014
Received: September 3, 2014

Dear Ms. Choi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141765

Device Name

FDR D-EVO Flat Panel Detector System (DR-ID600)

Indications for Use *(Describe)*

The Wireless/Wired FDR D-EVO 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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment B: K141765, 510(k) Summary

FUJIFILM
Fujifilm Medical Systems, USA

510(k) Summary

FDR D-EVO Flat Panel Detector System (DR-ID600)

Date: September 2, 2014

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

Contact Person:

Name: Katherine Y. Choi, RAC
Title: Regulatory Affairs Lead
Telephone: (203) 602-3568
Facsimile: (203) 602-3785

Identification of the Device:

Proprietary/Trade Name:	FDR D-EVO Flat Panel Detector System (DR-ID600)
Classification Name:	Stationary x-ray system
Regulations Number:	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 Flat Panel Detector System (DR-ID600), K132509 cleared 11/25/2013

I. DEVICE DESCRIPTION

Fujifilm's FDR D-EVO Flat Panel Detector System (DR-ID600) is a portable digital detector system that interfaces with, and acquires and digitizes x-ray exposures, from standard radiographic systems. The FDR D-EVO 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 exams.

The design modification made to the FDR D-EVO is adding Fujifilm's new post image processing algorithm called 'Virtual Grid Software'. The Virtual Grid Software is designed to improve image contrast in general radiographic images by reducing the effects of scatter radiation, primarily for exams acquired without a grid. Based on the displayed image, the user can decide whether or not to apply the Virtual Grid image processing by turning it ON or OFF as they see fit.

The Virtual Grid Software will be available as option to be installed with the FDR D-EVO's acquisition workstation, FDX Console. This Software will also be made available with all other legally marketed Fujifilm DR Systems that use the FDX Console as the acquisition workstation, since this post-processing algorithm does not depend on how the image is acquired, or with what acquisition device.

II. INDICATIONS FOR USE

The Wireless/Wired FDR D-EVO 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 is not intended for mammography, fluoroscopy, tomography, and angiography applications.

III. SUBSTANTIAL EQUIVALENCE

The modified FDR D-EVO FPD System (DR-ID600) is substantially equivalent to the following legally marketed device.

Legally Marketed Device	510(k) #	Clearance Date
FDR D-EVO Flat Panel Detector System (DR-ID600)	K132509	11/25/2013

Adding the Virtual Grid Software to FDR D-EVO (DR-ID600) does not affect the intended use or alter the fundamental scientific technology of the legally marketed device, K132509. The modified device's detector characteristics including Fujifilm's unique Irradiated Side Sampling (ISS) design delivering high image quality and wireless communication features remain unchanged, and the modified FDR D-EVO (DR-ID600) system virtually maintains the same functional and technical requirements as the currently-cleared predicate DR-ID600 system.

IV. SUMMARY OF STUDIES

Non-clinical Performance Data: The modified FDR D-EVO FPD System (DR-ID600) conforms to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 62366, IEC 62494-1 and DICOM. As required by the risk analysis, all verification and validation activities for the Virtual Grid Software were performed and the results were satisfactory. Additionally the bench testing and image quality evaluation further demonstrated the Virtual Grid processing algorithm yields an improvement in image contrast and quality, for those images acquired without an anti-scatter grid. The results of the bench testing and image evaluation are provided in the submission.

Clinical Performance Data: The design modification does not require clinical studies. The substantial equivalence has been demonstrated by non-clinical studies.

V. CONCLUSION

Based upon the supporting data summarized above, we concluded the modified FDR D-EVO Flat Panel Detector System (DR-ID600) is as safe and effective as the legally marketed device K132509 and do not raise different questions of safety and effectiveness than K132509.