DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 5, 2015

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

Re: K152138
Trade/Device Name: FDR D-EVO GL Flat Panel Detector System (DR-ID 1300)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 14, 2015
Received: October 15, 2015

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

Robert Ochs, Ph.D.
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)*
K152138

Device Name
FDR D-EVO GL Flat Panel Detector System (DR-ID 1300)

Indications for Use *(Describe)*
The FDR D-EVO GL 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 exams wherever conventional film/screen or CR systems may be used. This device is used to capture anatomic regions that are too large for conventional CR/DR format sizes. FDR D-EVO GL 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

FDR D-EVO GL Flat Panel Detector System (DR-ID1300)

Date: October 30, 2015

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 Manager
Telephone: (203) 602-3568
Facsimile: (203) 602-3785

Identification of the Device:

Proprietary/Trade Name:	FDR D-EVO GL Flat Panel Detector System (DR-ID1300)
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 Devices:

Device Name	510(k) #	Clearance Date
FDR D-EVO II Flat Panel Detector System (DR-ID1200)	K142003	10/21/2014
FDR Image Stitching Option	K101686	10/29/2010

I. DEVICE DESCRIPTION

Fujifilm's FDR D-EVO GL FPD System (DR-ID1300) is a digital detector system that interfaces with, and acquires and digitizes x-ray exposures from, standard radiographic systems. The DR-ID1300 is designed to be used in any environment that would typically use a radiographic cassette for examinations of adults and pediatrics including long-length exams where anatomic regions that are too large for conventional CR/DR format sizes, such as the entire spine or lower extremities, can be captured. The DR-ID1300 employs a new DR detector with a large exposure area size of ~ 17 x 49 inches. The detector can be placed in an appropriate stand for upright exams.

Unlike DR stitching which typically requires multiple exposures, the DR-ID1300 needs a single exposure to capture the long view exams, therefore it requires less time in acquiring an image and is unlikely to be affected by patient movement. It not only eliminates the need of precise X-ray tube rotation control but also removes the need of exposing overlapping area when taking multiple exposures. Also requiring a single exposure streamlines the user's workflow.

The DR-ID1300 can be used with any legally-marketed and appropriately certified X-ray source. However, use of the full detector area may require an increased source-to-image distance and increased technique factors which may exceed the capabilities of some x-ray systems. If the DR-ID1300 is used with the optional Hand Switch Interface Box, a connection to the X-ray source/generator's timing signals (prep and exposure signals) is necessary. Even if such timing signals are not available, the DR-ID1300 can acquire an image using Automatic x-ray detection function (known as 'SmartSwitch' in the US), so the limitation is negligible. In order to use the full effective area (~17x49") of the DR-ID1305SE detector, the X-ray source must be able to provide a large enough radiation field size to cover the entire effective area.

II. INDICATIONS FOR USE

The FDR D-EVO GL 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 exams wherever conventional film/screen or CR systems may be used. This device is used to capture anatomic regions that are too large for conventional CR/DR format sizes. FDR D-EVO GL is not intended for mammography, fluoroscopy, tomography, and angiography applications.

III. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Fujifilm's FDR D-EVO GL FPD System (DR-ID1300) introduces the new DR-ID1305SE detector with a large ~17x49" exposure/active area, which allows a wider range of the general purpose radiography including long-view exams. All the major detector characteristics that may affect the image quality are substantially equivalent to the legally marketed DR-ID1201SE detector in K142003. For example, scintillator material (gadolinium oxysulfide (GOS)), indirect conversion method with Fujifilm's unique Irradiated Side Sampling (ISS) technology, pixel pitch (150µm), and resolution (16 bit) are the same. The difference in MTF measurements is negligible, and the difference in DQE (Detective Quantum Efficiency) measurement is insignificant. Because of DR-ID1305SE's large exposure/active area, appearance, weight, pixel matrix, external dimensions as well as preview time and cycle/exposure time are different from DR-ID1201SE. The new DR-ID1305SE detector supports wired data connection. Also FDR D-EVO GL FPD System (DR-ID1300)'s system configurations are very similar to the FDR D-EVO II in K142003, but a later version of FDX Console will support the DR-ID1300.

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IV. SUBSTANTIAL EQUIVALENCE

Fujifilm FDR D-EVO GL FPD System (DR-ID1300) is substantially equivalent to the following legally marketed devices.

Legally Marketed Device	510(k) #	Clearance Date
FDR D-EVO II Flat Panel Detector System (DR-ID1200)	K142003	10/21/2014
FDR Image Stitching Option	K101686	10/29/2010

Both the new FDR D-EVO GL and legally marketed FDR D-EVO II are digital detector systems that are used to acquire x-ray exposures. Both systems are indicated for general purpose radiography including pediatric exams, but DR-ID1300 can be additionally used for long view exams where anatomic regions that are too large for conventional CR/DR format sizes, such as the entire spine or lower extremities, can be captured. This long-view exam indication is very similar to another legally marketed K101686 FDR Image Stitching Option.

Most detector characteristics remain unchanged, and the image quality is substantially equivalent to the legally marketed FDR D-EVO II.

V. SUMMARY OF STUDIES

Non-clinical Performance Data: FDR D-EVO GL FPD System (DR-ID1300) 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. 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. As required by the risk analysis necessary verification and validation activities were performed. For example, software changes were successfully evaluated according to the FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (*issued on May 11, 2005) based on a moderate level of concern. Cybersecurity recommendations of the FDA guidance, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (issued on October 2, 2014) were followed. Given that the new DR-ID1305SE detector's performance characteristics are equivalent to the currently marketed FDR D-EVO II detector in K142003, bench testing was conducted to evaluate the long view attributes that are unique to the DR-ID1300 system.

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

VI. CONCLUSION

Based upon the supporting data summarized above, we concluded the FDR D-EVO GL Flat Panel Detector System (DR-ID1300) is as safe and effective as the legally marketed devices K142003 and K101686, and does not raise different questions of safety and effectiveness than the predicate devices.