DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 24, 2017

FUJIFILM Medical Systems U.S.A., Inc.
Peter Altman
Regulatory and Quality Consultant
419 West Avenue
Stamford, Connecticut 06902

Re: K170858
Trade/Device Name: FDR AQRO (DR-XD 1000)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: March 20, 2017
Received: March 22, 2017

Dear Peter Altman:

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,

For

Robert A. 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)*
K170858

Device Name
FDR AQRO (DR-XD 1000)

Indications for Use *(Describe)*

The FDR AQRO (DR-XD 1000) is a digital mobile X-ray system intended for use in general purpose radiography for generating radiographic images of human anatomy, including adult, pediatric, and neonatal exams.
The FDR AQRO is not intended for mammography.

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)*

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510(k) Summary

FDR AQRO (DR-XD1000)
Mobile X-ray System

Date: March 20, 2017

Submitter's Information:

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

Contact Persons:

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Identification of the Device:

Proprietary/Trade Name:	FDR AQRO (DR-XD1000)
Classification Name:	Mobile X-ray system
Regulations Number:	21 CFR 892.1720
Product Codes:	IZL
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Mobile X-ray System

Identification of the Legally Marketed Predicate Device:

Sirius Starmobile Tiara, K143537 cleared 3/6/2015

Classification Name:	Mobile X-ray system
Regulations Number:	21 CFR 892.1720
Product Codes:	IZL
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Mobile X-ray System

I. DEVICE DESCRIPTION

FUJIFILM's FDR AQRO (DR-XD1000) is a compact, economical, lightweight, non-motorized, low power (2.5 kW), mobile X-ray system designed to work with FUJIFILM's GOS and CsI scintillator FDR D-EVO2 (DR-ID 12XXSE) family of digital X-ray detectors coupled. The D-EVO2 detectors received clearance on 7/23/2014 via 510(k) K142003.

The FDR AQRO includes a built-in operation console. The AQRO's console uses Version 10.0 of Fujifilm's FDX Console Software. This software received 510(k)

clearance via K170451 on 3/16/2017. The console software includes Virtual Grid 2 (VG2) Image Processing functionality. The VG2 function allows using the mobile X-ray system without a physical grid, resulting in a dose reduction of up to 50% (when compared to using a physical grid). The Virtual Grid 2 Image Processing software received clearance on 4/8/2016 via K153464.

The reduction in the external dimensions of FDR AQRO enables smooth movement in the hospital and at the bedside because of an integrated X-ray tube and high-voltage generator (mono-block) that eliminates the need for High Voltage cables and utilizes less space.

A high performance Li-ion battery provides up to twelve (12) hours of continuous use (at ~20 exposures/hour) with a quick full charge in four hours. A quick charge of 15 minutes provides one hour of usage. Exposure may also be made when the AC power cord is plugged in.

II. INDICATIONS FOR USE

The FDR AQRO (DR-XD1000) is a digital mobile X-ray system intended for use in general purpose radiography for generating radiographic images of human anatomy, including adult, pediatric, and neonatal exams. The FDR AQRO is not intended for mammography.

III. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

	Subject Device FDR AQRO (DR-XD1000)	**Predicate Device K143537, cleared Mar 6, 2015 Sirius Starmobile Tiara**
Indications for Use		
	The FDR AQRO (DR-XD1000) is a digital mobile X-ray system intended for use in general purpose radiography for generating radiographic images of human anatomy, including adult, pediatric, and neonatal exams. The FDR AQRO is not intended for mammography.	The Mobile X-ray Unit Sirius Starmobile Tiara is a general radiography system and is composed of the X-ray high voltage generator, X-ray tube, support unit, and digital radiograph device (DR-ID 800) made by Fujifilm Corporation. This device is designed for pediatric and adult patients. It is intended for use in general radiography of the head, body, or extremities including pediatric exams. The device output can provide an aid to diagnosis when used by a qualified physician.
General Characteristics		
Weight	90kg	420kg
Dimensions	600x851x1460 mm	575x1236x1780 mm
Energy Source	Batteries charged by AC line	Batteries charged by AC line
Move	Human-powered traveling	electric-powered traveling

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	Subject Device FDR AQRO (DR-XD1000)	Predicate Device K143537, cleared Mar 6, 2015 Sirius Starmobile Tiara
User Interface	Up-Down pushbuttons for kV and mAs. Software Driven Touch Panel LCD.	Up-Down pushbuttons for kV and mAs. Software Driven Touch Panel LCD.
X-ray Characteristics		
Radiography ratings	2.5kW	32kW
Tube voltage	40 to 100 in 1kV steps	40 to 130 in 1kV steps
Maximum tube current	35mA (automatically set according to tube voltage)	400mA (automatically set according to tube voltage)
mAs	0.25-25mAs	0.5-320mAs
X-ray tube focal spot size	1.7 x 2.4 mm	0.9x1.3 mm:Small focus 1.7x2.4 mm:Large focus
X-ray tube maximum anode heat capacity	35kJ (50kHU)	100kJ(140kHU)
X-ray tube target angle	16 degree	17 degrees
X-ray tube inherent filtration	1.3 mmAl equivalent	1.0 mmAl equivalent
X-ray tube Added filter	N/A	0.3 mmAl equivalent
X-ray beam limiting device illuminance of light field	200 lx or over (Note: at SID 100cm)	160 lx or over (Note: at SID 100cm)
X-ray beam limiting device timer for light field	30 seconds(This setting can be changed to 60 sec., 90 sec, 120 sec.or 180 sec. in the service setting)	30 seconds
X-ray beam limiting device inherent filtration	1.2 mm Al equivalent	1.2 mm Al equivalent
Total filtration	2.5 mm Al equivalent	2.5 mm Al equivalent
Maximum SID to floor	2000mm	2010mm
Tube arm reach	1200mm	1330mm
Detector Characteristics		
Sizes	24x30cm, 17x14in, 17x17in	24x30cm, 17x14in, 17x17in
Family	FUJIFILM Flat Panel Detector “D-EVO2” (DR-ID12xxSE) K142003	FUJIFILM Flat Panel Detector “D-EVO” (DR-ID6XXSE) included in the DR-ID800 of the Sirius Starmobile Tiara K132509

	Subject Device FDR AQRO (DR-XD1000)	Predicate Device K143537, cleared Mar 6, 2015 Sirius Starmobile Tiara
Scintillator	GOS and CsI	GOS and CsI
DQE (RQA5, 1 lp/mm, 1mR) – detector alone, without tabletop	30% (GOS) 54% (CsI)	29% (GOS) 53% (CsI)
MTF (RQA5, 2 lp/mm)	32% (GOS) 54% (CsI)	32% (GOS) 52% (CsI)

Even though the subject device is small and compact, it still provides the ability to maneuver and perform all the typical functions required of a mobile x-ray system. The beam coverage of the subject device is equivalent to the predicate device because the focal spot size is the same as predicate. Anode heat capacity of the subject device is less but the maximum mAs is also small so it will not impact the ability to perform exams. Acceptable image quality can be obtained with the FDR AQRO despite the smaller values of kV and mAs because of the highly sensitive detector system and the VG2 software.

The D-EVO II and D-EVO detectors, DR-ID12xxSE and DR-ID6xxSE used in the FDR AQRO and Sirius Starmobile Tiara respectively, have the same Indications for Use. FDR D-EVO II detectors' scintillator materials (GOS or CsI), indirect conversion method (a-Si), Fujifilm's unique ISS technology, readout properties, 150µm pixel pitch, and 16 bit-depth remain the same as the D-EVO detectors. The MTF and DQE measurements are very similar between FDR D-EVO II and D-EVO detectors. While DR-ID12xxSE and DR-ID6xxSE are wireless detectors, the wireless feature in DR-ID12xxSE has been improved by expanding operating frequency options, and adding new wireless components. The active area size and pixel matrix of the DR-ID12xxSE detectors are only slightly different from the predicate device (K132509). . In general the detectors used with both systems have the same physical and technical characteristics and their performance is substantially equivalent (note that the FDR D-EVOII Flat Panel Detector System (DR-ID1200) received clearance using the FDR D-EVO Flat Panel Detector System (DR-ID600) as the predicate device).

IV. SUBSTANTIAL EQUIVALENCE

The FDR AQRO (DR-XD1000) is substantially equivalent to the following legally marketed device:

Legally Marketed Device	510(k) #	Clearance Date
Sirius Starmobile Tiara	K143537	3/6/2015

Both systems, the subject device and the predicate (K143537), are intended for use in general purpose radiography for generating radiographic images.

Both the subject device, FDR AQRO (DR-XD 1000), and the predicate device, Sirius Starmobile Tiara (K143537), are mobile X-ray systems and have similar Indications For Use, i.e., general purpose radiography of adult and pediatric patients, although the FDR AQRO is also indicated for use with neonatal patients. The key technological characteristics of the subject device and the predicate device are

similar and the differences do not affect the IFU. Both systems use detectors that are substantially equivalent.

V. SUMMARY OF STUDIES

Non-clinical Performance Data: The FDR AQRO conformity includes the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 62366, IEC 62494-1, DICOM 3.0, IEC 60601-2-54, IEC 60601-1-3, and IEC 60601-1-6. In addition the device complies with the requirements of 21 CFR Subchapter J, Electronic Product Radiation Control. As required by the risk analysis, all verification and validation activities for the FDR AQRO were performed and the results were satisfactory. The submission contains sample phantom images.

Clinical Performance Data: The submission contains sample clinical images.

VI. CONCLUSION

Based upon the supporting data summarized above, we concluded the FDR AQRO is as safe and effective as the legally marketed device K143537 and does not raise different questions of safety and effectiveness than K143537.