K120629

FUJIFILM
Fujifilm Medical Systems, USA

AUG 28 2012

510(k) Summary
FDR Go Flex (DR-ID700)

Flat Panel Detector System

Date: February 22, 2012

Submitter's Information:

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

Contact Person:

Name:	Peter Altman
Title:	Regulatory Consultant
Telephone:	(203) 602-3576
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Identification of the Proposed Device:

Proprietary/Trade Name:	FDR Go Flex (DR-ID700)
Classification Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Regulations Number:	21 CFR 892.1650
Product Codes:	90 MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector

I. INDICATIONS FOR USE

The FDR Go Flex is intended to capture for display radiographic images of human anatomy. It is intended for use in general radiographic applications wherever conventional film/screen or CR systems may be used. The FDR Go Flex is not intended for mammography, fluoroscopy, tomography, and angiography applications.

II. DEVICE DESCRIPTION

The proposed device, the FDR Go Flex (DR-ID700), is a modification of the Wireless/Wired FDR D-EVO (DR-ID600 w/DR-ID601SE) Flat Panel Detector System, K103596, cleared on 3/29/2011 (submitted as a Special 510(k)) and the Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE), K111548, cleared on 8/30/2011. The FDR D-EVO Flat Panel Detector System (DR-ID600) cleared on 3/29/2011 was a modification of the FDR D-EVO (DR-ID600) Flat Panel Detector, K100762, cleared on 7/15/2010. The FDR D-

EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE cleared on 8/30/2011 was a modification of the system cleared on 3/29/2011.

The FDR Go Flex is a portable digital FPD system that acquires and digitizes x-ray exposures from standard radiographic systems and is designed to be used in any environment that would typically use a radiographic cassette. However, the FDR Go Flex is more portable than its predecessors given its smaller size and ability for all components to operate using battery power in a fully wireless configuration (no cable connections are required between the FDR Go Flex components, although it will remain possible to physically connect components if the user so desires). Note: Only wireless communication is supported between detectors and the Utility Box.

The indirect X-ray conversion method using GOS and CsI Scintillators, and FUJIFILM's unique Irradiated Side Sampling design, delivering high image quality, remained unchanged in the proposed device.

Since the detectors (DR-ID601SE, DR-ID602SE, and DR-ID611SE) are capable of automatically detecting X-ray, direct connection with the X-ray system is not needed.

III. SUMMARY OF STUDIES

The FDR Go Flex flat panel detector system successfully completed internal and international IEC testing requirements. In addition, the FDA Draft Guidance Document, *Radio-Frequency Wireless Technology in Medical Devices*, issued on January 3, 2007 was followed for the wireless feature.

IV. SUBSTANTIAL EQUIVALENCE

The proposed device, the FDR Go Flex (DR-ID700), is a modification of the Wireless/Wired FDR D-EVO (DR-ID600 w/DR-ID601SE) Flat Panel Detector System, K103596, cleared on 3/29/2011 (submitted as a Special 510(k)) and the Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE), K111548, cleared on 8/30/2011. The FDR D-EVO Flat Panel Detector System (DR-ID600) cleared on 3/29/2011 was a modification of the FDR D-EVO (DR-ID600) Flat Panel Detector, K100762, cleared on 7/15/2010. The FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID611SE cleared on 8/30/2011 was a modification of the system cleared on 3/29/2011. All detectors (DR-ID601SE, DR-ID602SE, and DR-ID611SE) used with the FDR Go Flex are capable of automatically detecting X-ray, a feature cleared in the latest predicate device.

V. CONCLUSION

The FDR Go Flex (DR-ID700) flat panel detector system is substantially equivalent to the cleared predicate devices and conforms to applicable medical device safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 28 2012

Mr. Peter Altman
Regulatory Consultant
FUJIFILM Medical Systems USA, Inc.
419 West Avenue
STAMFORD CT 06902

Re: K120629
Trade/Device Name: FDR Go Flex (DR-ID700)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 30, 2012
Received: August 1, 2012

Dear Mr. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120629

Device Name: FDR Go Flex (DR-ID700)

Indications for Use:

The FDR Go Flex is intended to capture for display radiographic images of human anatomy. It is intended for use in general radiographic applications wherever conventional film/screen or CR systems may be used. The FDR Go Flex is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
OIVD
510k K120629/S001