FUJIFILM
Fujifilm Medical Systems, USA

SEP 30 2011

K111965

Special 510(k) Premarket Notification Summary for Wired/Wireless FDR D-EVO with X-ray Detection Feature

Date: June 29, 2011

Contact Person:

Name:	Debbie Peacock
Title:	Regulatory Affairs Manager
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Identification of Device:

Proprietary/Trade Name:	Wired/Wireless FDR D-EVO with X-ray Detection Feature
Classification Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Classification:	Panel: Radiology
CFR Section:	21 CFR 892.1650
Product Codes:	90 MQB
Common Name:	Flat Panel Digital Detector

I. INDICATIONS FOR USE

The Wired/Wireless 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 wherever conventional film /screen or CR systems may be used. The FDR D-EVO (DR-ID600) is not intended for mammography, fluoroscopy, tomography and angiography applications.

II. DEVICE DESCRIPTION

The Wired/Wireless FDR D-EVO (DR-ID600/DR-ID601SE) flat panel detector (FPD) system is a digital imaging system used with diagnostic x-ray systems. It includes a Fujifilm D-EVO detector, Fujifilm D-EVO system control cabinet, and power supply unit. Images captured with the flat panel digital detector can be communicated to the operator console via tethered connection. Data captured via operator console is sent electronically to the Fujifilm FDX Console to be displayed on the monitor.

Wired/Wireless FDR D-EVO flat panel detector is an indirect-conversion amorphous silicon (a-Si) portable flat panel detector utilizing GOS (Gadolinium OxySulfide) as a scintillator. Wired/Wireless FDR D-EVO detector has Fuji's unique Irradiation Side Sampling system (hereinafter "ISS system").

The X-ray Detection Feature is a minor change to our cleared Wired/Wireless FDR D-EVO FPD detector system which eliminates the need for an electrical interface between the D-EVO system's DR-ID 600 MP and the x-ray exposure system. This is accomplished by incorporating X-ray sensors into the exposure surface of the proposed Wired/Wireless FDR D-EVO Flat Panel Detector.

There is no difference in preparation between both the predicate and proposed device. In both cases, the FPDs are informed that an x-ray exposure is imminent by selecting an anatomical menu at the acquisition workstation. Once the anatomical menu is selected, the detectors become "ready" for the exposure. Ready indicators illuminate on both the detector and the acquisition workstation signaling to the technologist that an exposure can be made.

SUMMARY OF STUDIES

Wired/Wireless FDR D-EVO with X-ray Detection Feature has successfully completed internal and international IEC testing requirements, as well as Verification and Validation Studies, and the following anthropomorphic phantom image evaluation.

Identically exposed and processed anthropomorphic phantom image pairs (proposed device vs. predicate device) were judged by 3 Fujifilm Imaging Specialists, as well as a board-certified radiologist (See Section 18, Performance Testing). No participant was able to visualize the X-ray sensors, and all participants found the D-EVO images with the X-ray Detection Feature were diagnostically equal to the predicate device images.

III. SUBSTANTIAL EQUIVALENCE

The Wired/Wireless FDR D-EVO with X-ray Detector Feature is a modification to Fuji's Wired/Wireless FDR D-EVO Flat Panel Detector System, K103596, cleared by CDRH on 03/29/11. This feature is the only difference between the proposed and predicate device.

IV. CONCLUSION

The Wired/Wireless FDR D-EVO with X-ray Detection Feature is substantially equivalent to the cleared predicate Wired/Wireless FDR D-EVO Flat Panel Detector 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

Ms. Debra A. Peacock
Regulatory Affairs Manager
Fuji Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

AUG 23 2013

Re: K111865
Trade/Device Name: Wireless/Wireless FDR D-EVO with X-ray Detection Feature
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 16, 2011
Received: August 17, 2011

Dear Ms. Peacock:

This letter corrects our substantially equivalent letter of September 30, 2011.

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
Acting 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): K111865

Device Name: Wired/Wireless FDR D-EVO with X-ray Detection Feature

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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 Device (OIVD)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111865