K080945

APR 18 2008

FUJIFILM
Fujifilm Medical Systems, USA

510(k) Summary

Date: March 7, 2008

Contact Person:

Name:	Debbie Peacock
Title:	Regulatory Coordinator
Telephone:	(203) 602-3774
Facsimile:	(203) 363-3813

Identification of Device:

Proprietary/Trade Name:	FUJIFILM FCR Go
Classification:	Class II
Classification Name:	Mobile X-Ray System
Product Code:	IZL
Common Name:	Mobile X-Ray System

I. INDICATIONS FOR USE

The FCR Go is indicated for use in generating radiographic images of the human anatomy. This device is not intended for mammographic applications.

II. DEVICE DESCRIPTION

The FCR Go battery powered, mobile x-ray system features a built-in Carbon XL CR reader and a notebook version of the CR Console (Flash IIP) or technologist console. Because the CR reader and CR console are incorporated in the equipment, the images are available to the technologist in a very short time, allowing the technologist to assure the exam has been performed adequately, minimizing return trips. Wireless communication is available, as an option, for updates to the patient worklist from the RIS/HIS. The FCR Go uses the same Image Plates (IPs) and cassettes used with other FCR systems.

The FCR Go provides smooth and quiet motorized travel capability via rear wheels independently driven by dual motors, a versatile radiography range through the telescopic arm, and easy-to-operate positioning of detector cassette providing sharp image quality with a short exam completion time.

Radiographic technique and exposure settings (kV, mAs) can be set up on the generator's control panel, as well as pre-configured from the CR console, based on exam type and typical recommended pre-programmed settings.

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10. Indications for Use:

Proposed FCR Go IFU:
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Predicate Indications for Use:

- The Mobilett XP CR is a radiographic system designed for use in wards, intensive care and premature birth wards, pediatric and emergency departments, operating theatres as well as the central X-ray department.

- The GE Definium AMX 700 is indicated for use in generating radiographic images of the human anatomy. This device is not intended for mammographic applications.

11. Confidentiality:

We consider all information contained in this submission as well as its existence to be Confidential and request FDA to consider it as such. Fuji requests that FDA not make public disclosure of this information without prior consultation with Fuji as provided by 21 CFR 20.45.

If you have any additional questions, please phone me at (203) 602-3774, or fax (203) 363-3813, or e-mail @ debbie.peacock@fujimed.com.

Sincerely,

Debra A. Peacock

Debra A. Peacock
Regulatory Coordinator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2008

Fujifilm Medical Systems, USA, Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer, Medical Business Unit
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K080945
Trade/Device Name: FCR Go
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: April 2, 2008
Received: April 3, 2008

Dear Mr. Rongero:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080945

Device Name: FCR Go

Indications for Use:

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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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080945