K073650

EXHIBIT 2
510(k) Summary

FUJIFILM USA
419 West Avenue
Stamford, CT 06902
Phone 203/324-2000
Fax 203/353-0926

FEB - 6 2008

Contact: Debbie Peacock, Regulatory Coordinator
Date Prepared: December 11, 2007

1. Identification of the Device:
   Proprietary-Trade Name: FUJIFILM Unity SpeedSuite
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR and MQB
   Common/Usual Name: General purpose diagnostic X-ray Unit with digital imaging receptor.

2. Equivalent legally marketed devices: This notification is for a MODIFIED device. This device COMBINES three 510(k) cleared devices, the SEDECAL Universal Radiographic Systems K012546, the detector used in the Fujifilm Fuji Computed Radiography (FCR) Velocity Image Reader K033561, and the Fuji Medical CR/DR Console, Flash IIP. This combination is functionally identical to a SEDECAL cleared device, Sedecal URS LP X-Ray Units with Digital Detector, K042876.

3. Indications for Use (intended use): Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. Description of the Device: The FUJIFILM DR Unity SpeedSuite is a stand-alone X-ray exposure system comprised of a U- arm (manufactured by Sedecal) that incorporates the following:
   - Fuji's image reader equipped with HD Linescan technology
   - Fuji's CR/DR Console (IIP), and
   - Sedecal's X-ray source and U-Arm system (Verso).

   Since both are paired, the height and angle can be flexibly changed while maintaining their positional relationship. This system enables you to make an exposure not only at supine or upright position but also at any other desired positions. Images taken by the Unity system are sent to Fuji's IIP (CR/DR Console) to be processed. There is an automatic collimator made by Huestis attached to the tube head. The x-ray tube is manufactured by Toshiba

5. Safety and Effectiveness, comparison to predicate device. The results of bench user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart, FUJIFILM Unity SpeedSuite

Characteristic	**Sedecal URS X-Ray Units with Digital Detector #K042876 (Predicate Device)**	**FUJIFILM Unity SpeedSuite (Proposed Device) (Combines three cleared devices: Fuji K033561/K041990 AND Sedecal K012546)**
Intended Use:	General purpose diagnostic X-ray unit	SAME
User Interface	Depends on Control Console option chosen. Mainly dedicated touch controls	Software Driven Touch Panel LCD, + remote control unit + remote console
Maximum output	Depends on model of generator chosen. Models available from 30 kW to 64 kW	Depends on model of generator chosen. Models available from Sedecal range from 30kW to 80 kW
Image Acquisition	Digital: CANON CXDI-50G. K031447	Digital: Fuji Computed Radiography (FCR) Velocity K033561
Digital Panel Size	Up to 14" x 17" active area	17" x 17" active area
Digital Resolution	160 micron pixels, with approximately 6 million pixels	100 micron pixels, 15 million pixels.
Method of Control	Dedicated push button Controls	Software Driven Touch Panel LCD
Collimator	Manual R302/A	Automatic, Huestis 150PBL

7. Conclusion After analyzing bench and standards testing data, it is the conclusion of FUJIFILM Medical Systems, USA that the FUJIFILM Unity SpeedSuite x-ray System is as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

FujiFilm Medical Systems USA, Inc.
% Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K073650
Trade/Device Name: FujiFilm Unity SpeedSuite (CR-IR-371)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: December 19, 2007
Received: December 26, 2007

Dear Mr. Kamm:

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): K073650

Device Name: FUJIFILM Unity SpeedSuite

Indications For Use:

FUJIFILM Unity SpeedSuite X-Ray System is Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073650