FEB 10 2000

FUJIFILM

I – Imaging & Information

FUJI MEDICAL SYSTEMS U.S.A., INC.

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K993861

510(k) Summary
[as required by 21 CFR 807.92]

Date Prepared [21 CFR 807.92(a)(1)]

November 12, 1999

Submitter's Information [21 CFR 807.92(a)(1)]

Fuji Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902
Telephone: (203) 602-3677
Facsimile: (203) 327-6485
Contact: Joseph M. Azary

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- Fuji Computed Radiography Dual Side Reading
- Fuji Computed Radiography Both Side Reading
- Fuji Computed Radiography FCR 5501D Dual Side Reader

The device common or classification names are: Computed radiography system, CR system, FCR system, digital imaging system.

Predicate Device [21 CFR 807.92(a)(3)]

Fuji identifies the predicate devices as follows:

Subject Device	FCR 5501D Dual Side Reader (Standard Pixel Density Image Mode)	FCR 5501D Dual Side Reader (High Pixel Density Image Mode)
Predicate Device	FCR 9501	FCR 9501HQ
510(k) for Predicate Device	K944046	K951373
Classification	Class II, 892.1900	Class II, 892.1900
Product Code	90LLZ and 90IXW	90LLZ and 90IXW

Description of the Device [21 CFR 807.92(a)(4)]

The Fuji Computed Radiography Dual Side Reading consists of an image reader (FCR 5501D Dual Side Reader) and Imaging Plates (described below). The image reader is cassetteless because the IPs are built-into this upright exam stand/reader. After exposure, the IP is in turn to the scanning, erasing, and holding areas. For the operator, this means that as soon as the IP is exposed , another is brought into the exposure area, without having to wait for reading and erasure.

As with other FCR image readers, the FCR 5501D Dual Side Reader will feature a photostimulable phosphor imaging plate composed of europium activated barium fluorohalide compounds in a crystal form held in an organic binder. The Imaging Plate used with the subject device (ST-55 BD) will have a transparent support, which will allow emission detection from both the support side and phosphor side of the IP.

IP Characteristic	ST-55 BD (Dual Side IP)	ST-V, ST-VA, ST-VN
Thickness	320 micrometers; thicker phosphor layer	230 micrometers
Protective Layer	Protective Layer is present	Protective Layer is present
Support Layer	Transparent Support	Non-transparent support
Light Shielding Layer	Not present	Light Shielding Layer present

Intended Use [21 CFR 807.92(a)(5)]

The indications for use of the Fuji Computed Radiography Dual Side Reading is the same as the predicate device: the identification, capture, digitization, and processing of diagnostic x-ray images, and associating patient and exam identification with the images.

Technological Characteristics [21 CFR 807.92(a)(6)]

The subject device represents a change to the predicate devices (FCR 9501 and FCR 9501HQ) that allows for reading on both sides of the imaging plate. The technology used in the subject device is described in a scientific article entitled "*Novel Computed Radiography System with Improved Image Quality by Detection of Emissions from Both Sides of an Imaging Plate*" by Satoshi Arakawa, Wataru Itoh, Katsuhiro Kohda, Toshiaki Suzuki.

The gray scale is 10 bits (1024 gray levels) for both the predicate and subject devices. The sampling raster of the subject device is identical to that of the predicate device. The one exception is that the subject device offers additional IP reading area sizes, such as 17x17 in., 17x14 in., and 18x43cm.

Performance Data [21 CFR 807.92(b)(1)]

Based on our scientific data we found the modulation transfer function (MTF) for the subject device is virtually identical to the MTF data for the predicate devices. Additionally, the relative detective quantum efficiency (DQE) for the subject device provides a 30-40% increase in relative DQE, as compared to the predicate device.

The subject device was tested by Underwriters Laboratories Inc. and found to conform to the UL Standard 2601-1 *Medical Electrical Equipment Part 1: General Requirements for Safety* (File E179671, Project 99SC47495).

Conclusion [21 CFR 807.92(b)(3)]

In conclusion, the Fuji Computed Radiography Dual Side Reading are nearly identical in design, materials, construction, and function to the predicate devices. The main difference is that the components of the subject device (image reader and imaging plate) have been modified in a manner that allows emission detection from both sides of the imaging plate.

For a radiographic imaging system, image quality is the principal area of concern for safety and effectiveness. The results of laboratory tests demonstrate the subject devices provide equivalent MTF and increased DQE. In fact, based on test data the dual side reading method enhances image quality.

The subject device conforms to UL Standard 2601-1 *Medical Electrical Equipment Part 1: General Requirements for Safety* (File E179671, Project 99SC47495).

We conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2000

Joseph M. Azary
Regulatory Affairs Coordinator
Fuji Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT 06902

Re: K993861
Fuji Computed Radiography Image Reader with Dual Side IP Reading
Dated: November 12, 1999
Received: November 15, 1999
Regulatory class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Mr. Azary:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 10(k) Number (if known): K993861

Device Name: Fuji FCR 5501D

Indications For Use:

The indications for use of the FCR 5501D is the same as the predicate device: the identification, capture, digitization, and processing of diagnostic x-ray images, *and associating patient and exam identification with the images.*

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993861

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)