K051553

FUJIFILM

I&I - Imaging & Information

FUJIFILM MEDICAL SYSTEMS USA, INC.

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JUL - 7 2005

510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, FUJIFILM Medical Systems, USA, Inc. herewith submits a 510(K) summary for the following device.

Submitter Name / Address:	FUJIFILM Medical Systems, USA, Inc. 419 West Avenue Stamford, CT 06902
Contact Person / Tel No.:	Rob Berry Director of Quality Assurance and Regulatory Affairs
Date Summary Prepared:	March 28, 2005
Establishment No.:	2443168
Trade/Proprietary Name:	Fuji Synapse Workstation Software
Common/Usual Name:	Medical Image Processing Workstation
Classification Name:	Picture archiving and communications system
Class/Panel:	Class II, 90-LLZ, 21CFR 892.2050
Predicate Device(s):	CR Console (Flash IIP), Fuji Medical Systems Light Beam Workstation, Amicas, Inc. IDS5/mx.net Workstation, Sectra Imtec AB

Device Description:

The Synapse Workstation provides viewing and manipulation of radiological data including images, reports, patient status, and clinical information.
The workstation utilizes a folder structure providing easy navigation and organization of images, studies, documents, etc. that most users are familiar with from Microsoft Explorer and other Windows applications. The workstation contains workflow scripting and hanging protocols designed to maximize productivity and allow each user to tailor the workstation operation to their individual needs.
In addition to common image manipulation functions such as window/level and window/width variation, magnification, density value, etc., the Synapse Workstation provides more advanced image processing, including processing of CR and CT images.

Intended Use:

Fuji Synapse Workstation Software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with Fuji Synapse PACS. The Fuji Synapse Workstation is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The Synapse Workstation can process medical images from the following modality types: plane X-ray radiography (including digital

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mammography), X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine and images from other DICOM compliant modalities.

Technological Characteristics and Predicates Devices:

The Fuji Synapse Workstation is comparable and substantially equivalent to the Light Beam Workstation manufactured by Amicas, Inc. as a PACS Workstation and is comparable and substantially equivalent to the image processing capabilities of the CR Console manufactured by Fuji.

Safety Information:

The Synapse Workstation Software introduces no new safety and efficacy issues other than those already identified with the predicate devices. The results of a hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the May 29, 1998 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The Instructions for Use contains precautions and warnings for safe and effective use of the device.

Potential hazards are identified through risk analysis and managed through the software development process and verification/validation testing.

The Synapse Workstation complies with the following mandatory and voluntary standards:

- ACR/NEMA DICOM Version 3.0 (Digital Imaging and Communications in Medicine) - developed by the American College of Radiology and the National Electrical Manufacturers Association. The Synapse DICOM Conformance Statement has been included in the Labeling section as Appendix F3.

Recommended Specifications for Workstation Hardware include compliance with the following standards:

- General Safety standards for all hardware: IEC60950 or equivalent.
- Information Technology Equipment, Radio Disturbance (Emissions) Characteristics-Limits and Methods of Measurements, IEC/CISPR 22 (EN55022)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 23 2011

Ms. Debra A. Peacock
Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD CONNECTICUT 06902 U.S.A.

Re: K051553
Trade/Device Name: Fuji Synapse Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 28, 2005
Received: June 29, 2005

Dear Ms. Peacock:

This letter corrects our substantially equivalent letter of July 7, 2005.

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 (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 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.

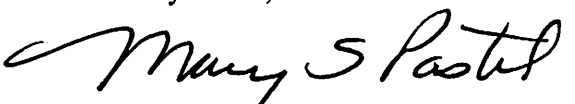
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications For Use

510(k) Number (if known): K051553

Device Name: Fuji Synapse Workstation

Indications For Use:

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The Synapse Workstation may be used for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible, displays. Synapse does not provide spatial frequency enhancement, dynamic range control, or multi-objective frequency image processing for DICOM MG "For Presentation" mammography images.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K051553