



Food and Drug Administration
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FUJIFILM Medical Systems U.S.A., Inc.
% Jyh-Shyan Lin
Senior Manager, Regulatory, Quality and Clinical Affairs
419 West Avenue
STAMFORD CT 06902

February 3, 2016

Re: K160108
Trade/Device Name: Synapse PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 15, 2016
Received: January 19, 2016

Dear Jyh-Shyan Lin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the typed name.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160108

Device Name
Synapse PACS

Indications for Use (Describe)

FUJIFILM Synapse PACS Software (client) is intended for use, as a web based application, on an off-the-shelf PC meeting or exceeding minimum specifications and networked with FUJIFILM Synapse PACS Software (Server). The FUJIFILM Synapse PACS Software 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 PACS Software can process medical images from the following modality types: plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine and images from other DICOM compliant modalities.

The FUJIFILM Synapse PACS Software enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, technologists and clinicians. These functions (MIP/MPR/Fusion) are not intended for Mammography use.

The FUJIFILM Synapse PACS Software may be used to process FUJIFILM's DICOM MG "For Processing" images and also 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 for mammography.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number: K160108

Date Prepared:

February 1, 2016

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.

419 West Avenue

Stamford, Connecticut 06902

Telephone: (301) 251-1092

Fax: (203) 602-3785

Contact: Jyh-Shyan Lin

Device Trade Name:

Synapse PACS

Device Common Names:

Picture Archiving and Communications System (PACS)

Device Classification Name:

System, Image Processing, Radiological

Product Code:

LLZ

Regulation Number:

21 CFR 892.2050

Device Class:

Class II

Panel:

Radiology

Predicate Devices:

- FUJIFILM Synapse Workstation Software ([K112439](#))
- Synapse MPR Fusion ([K113244](#))

1. Description of the Device

The proposed Synapse PACS Software is an implementation that combines capabilities of Synapse Workstation software (K112439) and Synapse MPR/Fusion software (K113244) in a single system, using the current Internet standards for Web clients and servers. The Synapse PACS Software and the predicate devices, i.e., Synapse Workstation Software (K112439) and Synapse MPR Fusion Software (K113244), are picture archiving and communication systems (as defined by 21 CFR 892.2050). Synapse PACS Software is the web based (client/server) application and implementation of the Synapse Workstation Software and the Synapse MPR Fusion Software. The Synapse PACS Software (**client**) is intended for use, as a web based application, on an off-the-shelf PC meeting or exceeding minimum specifications and networked with Synapse PACS Software (**server**). The Synapse PACS Software 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 PACS Software can process medical images from the following modality types: plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine and images from other DICOM compliant modalities. Synapse PACS Software enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies (K113244).

In summary, this 510(k) submission introduces the Synapse PACS with the web based (client/server) application and the ability to the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies.

2. Indication for Use

FUJIFILM Synapse PACS Software (client) is intended for use, as a web based application, on an off-the-shelf PC meeting or exceeding minimum specifications and networked with FUJIFILM Synapse PACS Software (Server). The FUJIFILM Synapse PACS Software 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 PACS Software can process medical images from the following modality types: plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine and images from other DICOM compliant modalities.

The FUJIFILM Synapse PACS Software enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, technologists and clinicians. These functions (MIP/MPR/Fusion) are not intended for Mammography use.

The FUJIFILM Synapse PACS Software may be used to process FUJIFILM's DICOM MG "For Processing" images and also 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 for mammography.

3. Substantial Equivalence Comparison

3.1 Device features and technological characteristics comparison

Table 1. Synapse PACS 5.1.0 vs. Synapse Workstation 3.3.0 (K112439)

Features	Synapse PACS 5.1.0 (This submission)	Synapse Workstation 3.3.0 (K112439)
Product availability	Provided as Software only	Provided as Software only
Operating Systems	Windows 7/8.1	Windows 2000/XP
Web Browser	Internet Explorer Version: 10 or 11 or Google Chrome	Internet Explorer
Database and file access method	Web based (http(s))	Web based (http(s))
Display of Digital Mammography Images	Yes	Yes
Process of Digital Mammography (Non-Processed or For Process) Images	Yes	Yes
On-demand access to database and images	Yes	Yes
Viewing study lists	Yes	Yes
Decompression for compressed images before display	Yes	Yes
Display images	Yes	Yes
Viewing Reports	Yes	Yes
Hanging Protocol	Yes	Yes
Spine Labeling	Yes	Yes
Reference line display	Yes	Yes
Key images identification	Yes	Yes
Link multiple series	Yes	Yes
Measurement Tools	Yes	Yes
Annotation Tools	Yes	Yes
Standard Image Manipulation Tools (Window width/level, Zoom, Pan, etc.)	Yes	Yes
FCR IPSS for Fuji-CR images	Yes	Yes
CT IPSS for CT images	Yes	Yes

Table 2. Synapse PACS 5.1.0 vs. Synapse MPR Fusion 2.5 (K113244)

Features	Synapse PACS 5.1.0 (This submission)	Synapse MPR Fusion 2.5 (K113244)
Product availability	Provided as Software only	Provided as Software only
Operating Systems	Windows XP/Vista/Windows 7	Windows 7, Windows 8.1 64bit
Web Browser	Internet Explorer Version: 10 or 11 or Google Chrome	Internet Explorer
Database and file access method	Web based (http(s))	Web based (http(s))
Orthogonal and Oblique Multi Planar Reconstruction (MPR)	Yes	Yes
Maximum, Average, and Minimum Intensity Projection (MIP, MPVR, MinIP)	Yes	Yes
Curved Multi Planar Reconstruction (CPR)	No	Yes
Independent Window/Level of upper and lower images in Fusion Study	Yes	Yes
Save Preferences by User Profile	No	Yes
Save Window/Level Preferences	Yes	Yes
Multi-Modal Fusion to include MR/PET/NM/and CT	Yes	Yes
Compare Current Study to previous study in Fusion View	Yes	Yes
Compare Current Study to Prior Study in Compare Mode	Yes	Yes
Manual Fusion Correction with Rigid Registration in Blend and overlay modes	No	Yes
Save series to Synapse PACS	Yes	Yes

3.2 Technology Similarities and Differences

Table 3. Synapse PACS 5.1.0 vs. Synapse Workstation 3.3.0 (K112439)

Technology	Synapse PACS 5.1.0 (This Submission)	Synapse Workstation 3.3.0 (K112439)
Image and Data Processing	Server Side	Client Side
Technology Platform (Synapse Client)	Platform Independent (Browser based UI)	Windows Active-X
Technology Platform (Synapse Server)	Windows Server	Windows Server
System Security	Windows Authentication	Windows Authentication
Programming Language(s) (Synapse Client)	Javascript (TypeScript), HTML5, CSS	C++, Active-X

Table 4. Synapse PACS 5.1.0 vs. Synapse MPR Fusion 2.5 (K113244)

Technology	Synapse PACS 5.1.0 (This Submission)	Synapse MPR Fusion 2.5 (K113244)
Image and Data Processing	Server Side	Client Side
Technology Platform (Synapse Client)	Platform Independent (Browser based UI)	Windows Native Application
Technology Platform (Synapse Server)	Windows Server	Windows Server
System Security	Windows Authentication	Windows Authentication
Programming Language(s) (Synapse Client)	Javascript (TypeScript), HTML5, CSS	C++

3.3 Device Specifications Comparison

Table 5. Synapse PACS 5.1.0 vs. Synapse Workstation 3.3.0 (K112439)

Specifications	Synapse PACS 5.1.0 (This Submission)	Synapse Workstation 3.3.0 (K112439)
Client O/S	Windows 7/8.1	Windows 2000/XP
Browser	Internet Explorer Version: 10/11 or Google Chrome	Internet Explorer
Server O/S	Windows 2008 R2, or 2012 R2 Server OS	Windows 2003, or 2008 Server OS
Database	Oracle	Oracle

Table 6. Synapse PACS 5.1.0 vs. Synapse MPR Fusion 2.5 (K113244)

Specifications	Synapse PACS 5.1.0 (This Submission)	Synapse MPR Fusion 2.5 (K113244)
Client O/S	Windows 7/8.1	Windows 2000/XP
Browser	Internet Explorer Version: 10 or 11 or Google Chrome	Internet Explorer
Server O/S	Windows 2008 R2, or 2012 Server R2 OS	Windows 2003, or 2008 Server OS
Database	Oracle	N/A

4. Safety Information

Synapse PACS introduces no new safety or efficacy issues other than those already indentified with the predicate device. The Risk Management and the results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.” The Synapse PACS labeling contains instructions for use and necessary cautions, warnings and notes to provide the safe and effective use of the device.

5. Testing and Performance Information

Synapse PACS is tested successfully with reference to its product requirements, as well as design verification and validation documents and traceability matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse PACS software, which is found to be safe and effective and substantially equivalent to the predicate devices.

Testing involved system level functionality test, component testing, verification testing, integration testing, usability testing, installation/upgrade testing, labeling testing, as well as the testing for risk mitigations associated with the risk management process. In addition, we conducted benchmark performance testing using actual clinical images to help demonstrate that the proposed device achieved the expected accuracy performance.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

6. Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate device.