FUJIFILM Corporation
% Ms. Senita Sims
Director, Document Management
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Ave
LEXINGTON MA 02421

March 26, 2019

Re: K190232
Trade/Device Name: Synapse PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 31, 2019
Received: February 6, 2019

Dear Ms. Sims:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190232

Device Name
Synapse PACS

Indications for Use *(Describe)*
FUJIFILM Synapse PACS Software is intended for use as a web based application on an off-the shelf PC which meets or exceeds minimum specifications and is networked with a FUJIFILM Synapse PACS server.

The FUJIFILM Synapse PACS Software can process medical images from DICOM compliant modalities and non-DICOM sources.

The FUJIFILM Synapse PACS Software provides toolsets for performing measurements on DICOM images, importing and presenting data from modalities (DICOM and non-DICOM), solving clinical calculations, and creating and distributing structured reports.

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. It enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies.

Typical users are radiologists, cardiologists, technologists, sonographers, technicians, nurses and clinicians.

MIP, MPR, and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5) 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

5a) Submitter

FUJIFILM Corporation
26-30, NISHIAZABU 2-CHOME MINATO-KU
TOKYO 106-8620
JAPAN
FDA Establishment Registration Number: 3005930550

Contact Person
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E-Mail: senita.sims@fujifilm.com
Date Prepared: February 1, 2019

5b) Device

Trade Name:	Synapse PACS
Common Name:	Medical Information and Image Management Software
Regulatory Class:	II
Classification Panel:	Radiology
Regulation Name:	Picture archiving and communications system
Regulation Number:	892.2050
Product Code:	LLZ

5c) Predicate Devices

Primary predicate
K160108 - FUJIFILM Medical Systems U.S.A., Inc. - Synapse PACS
Secondary predicate
K151859 - FUJIFILM Medical Systems U.S.A., Inc. - Synapse Cardiovascular
No reference devices were used in this submission.

5d) Device Description

The Synapse PACS which is the subject of this Premarket Notification Submission is a multipurpose, enterprise-wide application intended for communication, storage, display, printing, and processing of medical images. Its software components perform operations related to image manipulation and measurements relevant to radiology and cardiology. As a software-only device, it does not control image acquisition.

Typical users of Synapse PACs are radiologists, cardiologists, technologists, sonographers, technicians, nurses, and clinicians.

The software runs on standard PC equipment using MS Windows operating systems meeting minimum system requirements. An installed Synapse PACS system will typically be comprised of several Synapse PACS clients and one or more Synapse PACS servers

Synapse PACS accepts images and information from any DICOM-compliant acquisition device. In addition to system administrator tools, the device offers additional options for radiologist and cardiologist interpretation, in-house clinical review, and information access including reports, patient status, and clinical information acquired from various medical imaging and information systems. Options with clinical relevance are listed below:

- Image Display

Synapse PACS uses the Accusoft Medical Imaging toolkit for image processing. The brightness and contrast enhancements are implemented using the Accusoft toolkit. The Accusoft toolkit is also used to enlarge and reduce the images for display. Loading of images is done mainly with the Accusoft toolkit.

The Accusoft toolkit is used for saving the images using different forms of compression. Images are saved in DICOM format. The different types of compression allowed are uncompressed, Run-Length-Encoding (lossless), JPEG Lossless, and various degrees of JPEG Lossy. The compression scheme used for JPEG Lossy is a standard one, Discrete Cosine Transform (DCT). There is also an option for leaving the image files in their original format, using a straight copy. The straight copy option is used by the DICOM Server when receiving images because typically the image-generating instruments have already compressed the images.

- Image Quantification
    - Full measurement capabilities for DICOM-compliant ultrasound images
    - Particular support for 2-D, M-mode, Spectral Doppler, and Color Doppler calibration regions
    - Measurements made on automatically-magnified images to increase accuracy
    - Continuous image overlay of all measurements as they are performed
    - New measurement parameters and calculations may be created by FUJIFILM engineers
    - All programmed calculated measurement formulas can be viewed by the user
    - Automatic image calibration on DICOM images
- Clinical Reporting Application

The Clinical Reporting Application (CRA) is a Web application that provides structured reporting to Synapse. The CRA has pre-built, procedure specific, report templates to facilitate comprehensive and robust documentation. FUJIFILM engineers have the capability of customizing these report templates satisfy the imaging lab's individual requirements. The CRA is fully integrated with Synapse's clinical context and measurement (image quantification) capabilities.

- SWAT

The Synapse Web Administration Tool (SWAT) is a web-based tool that is used to configure, modify and maintain the Synapse system. The SWAT dashboard provides a graphical dashboard of pertinent information for Fujifilm field engineers and System Administrators. This simple static dashboard provides database-related content that is used to understand if the system is running well or encountering an issue.

- Desktop Agent

The Desktop Agent is a graphical interface used to provide the integration with third-party applications.

- Worklists

Worklists are filtered selections of patients and their respective studies collected from the Synapse database.

- PowerJacket

PowerJacket is a Web application that implements user-facing features such as displaying/filtering/sorting a study list of the patient and showing/editing study information such as notes, reports, and documents.

- General Purpose Importer

The General Purpose Importer (GPI) is a service that enables Synapse to received discrete data and non-DICOM images from modalities. These data are imported and available for the CRA to use in a report.

- Report Distribution Service

The Report Distribution Service (RDS) is a service that enables Synapse to distribute reports as HL7 results to downstream information systems.

5e) Indications for use

FUJIFILM Synapse PACS Software is intended for use as a web based application on an off-the shelf PC which meets or exceeds minimum specifications and is networked with a FUJIFILM Synapse PACS server.

The FUJIFILM Synapse PACS Software can process medical images from DICOM compliant modalities and non-DICOM sources.

The FUJIFILM Synapse PACS Software provides toolsets for performing measurements on DICOM images, importing and presenting data from modalities (DICOM and non-DICOM), solving clinical calculations, and creating and distributing structured reports.

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. It enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies.

Typical users are radiologists, cardiologists, technologists, sonographers, technicians, nurses and clinicians.

MIP, MPR, and 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.

5f) Comparison of Technological Characteristics

Comparison with K160108: Both versions Synapse PACS, the subject of this submission, and Synapse PACS, the primary predicate, are multipurpose, enterprise-wide applications that provide viewing and manipulation of radiological data including images, reports, patient status, and clinical information. They are used for radiologist interpretation, in-house clinical review, and physician desktop image and information access. Both include the ability to process and display images from plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from DICOM-compliant modalities, and both systems can be used to process DICOM MG “For Processing” (Fujifilm only) 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. Both the current device and K160108 Client display comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies.

Comparison with both predicates: Synapse PACS (current device), Synapse PACS (K161108), and Synapse Cardiovascular (K151859) accept images and information from any DICOM-compliant acquisition device. In addition, the reporting tools offer customization and advanced analysis capabilities, interactive diagrams, and auto-summary.

As native Windows programs, the Desktop Agent is also available to communicate with third-party dictation and clinical applications that are installed on the workstation. The Desktop Agent can notify these third-party applications when the clinical context in the Synapse Client running in the web browser changes. Additionally, the Desktop Agent can notify the Synapse Client when the clinical context in a third-party application changes.

Comparison with K151859: Synapse PACS (current device) and Synapse Cardiovascular are both designed to address multimodality viewing, advanced analysis, customized workflow automation through HIS, ADT/Orders, DICOM Modality Worklists, as well as Results and Billing integrations.
The high-level functionality of both systems is divided into three areas:

- Image Display
- Analysis
- Structured Reporting

Image Display
Both devices support the display of multiple image formats including DICOM, JPEG, TIFF, HP SONOS, AVI, DEFF, and others. They have several image-viewing options to allow for flexibility in image size and position on the screen. When viewing images on either product, the screen is organized to maximize the available pixels for digital images rather than controls, buttons, and icons. The default screens of each display permit two side-by-side, high-resolution viewing windows.

Virtually all manipulation of images can be performed by clicking on toolbar buttons or pressing keyboard keys. The controls of both are designed to be intuitive, requiring relatively brief instruction.

Transferring images to other storage devices, with or without compression, is also available with both devices.

Analysis
Off-line measurements and regional wall scoring are available with both products. They each have full measurement capabilities for 2-D, M-mode, Spectral Doppler, Color Doppler, and Vascular Ultrasound studies.

Many laboratories have custom measurements that they routinely make and may have calculations to perform based on those new measurements. Both the current and predicate K151859 Synapse devices allow the user to define new variables, define new measurements, and enter new equations that relate the variables. This new information can then be added to a report. Appropriate comments and checks for normal ranges for the new variables can also be added to the interpretation of both devices. These checks help ensure that the new equations have been entered correctly. The User Documentation describes how to add new variables, measurements, equations, comments, and checks on the normal ranges. The documentation also discusses the importance of testing and verifying the accuracy of the new equations and some guidance on how to proceed with the testing.

Both devices also have:

- Measurements made on automatically-magnified images to increase accuracy
- Continuous on-screen log of all measurements as they are performed

- New measurement parameters and calculations may be created by the user
- All programmed calculated measurement formulas can be viewed by the user
- Automatic image calibration on DICOM images
- Stress Echo Regional Wall Motion Scoring

Reporting
Both products generate reports based on the measurements, and the format of the reports can be modified by the user. As part of the reporting, the two products have preset comment lists available to the user to facilitate consistency within a lab or hospital; users can also add their own comments to customize the comment list. Patients and exam data are tracked via databases with both devices.

Both devices also have:

- Preset 2-D, M-mode, Doppler, Regional Wall Motion, Vascular, Cardiac Cath, Comment lists for rapid and consistent report generation
- Comment lists easily created and modified by user
- Old and current reports are accessible for review and printing
- Default set of report templates: Stress echo, Stress ECG, Transesophageal echo, Transthoracic echo, Pediatric echo, Fetal echo, EP, invasive and non-invasive vascular, cardiac catheterization, and nuclear

Specifications and technology are essentially identical between the current and primary predicate devices. The only difference is that the ActiveX component available in K160108 to allow users extra interactions with Microsoft Windows applications like copying images directly into the Microsoft Windows clipboard or dragging and dropping the images directly into external applications has been removed in the current device.

Comparison with both predicates: The current device and both predicates are software-only devices that use familiar internet browsers as their Graphical User Interface (GUI), allowing the user to rely on standard navigational tools such as forward, back, links, and favorites. All three operate on Microsoft Internet Explorer, while the current device and primary predicate devices also operate on Google Chrome.

Accepted methods for Verification and Validation testing were used for both the current and predicate devices. Software development and testing for both is in compliance with the IEC 62304 “Medical device software – Software life cycle processes” standard.

5g) Conclusions

Synapse PACS has the same general intended use, and similar indications for use, principles of operation, and technological characteristics as the predicate devices Synapse PACS (K160108) and Synapse Cardiovascular (K151859). Differences in features or functionality do not raise issues of safety or effectiveness. Thus, Synapse PACS is substantially equivalent to the primary predicate device.