FUJIFILM Healthcare Americas Corporation
Kulkarni Chaitrali
Sr. Regulatory Affairs Specialist
81 Hartwell Ave Suite 300
LEXINGTON, MASSACHUSETTS 02421

June 30, 2025

Re: K243647
Trade/Device Name: Synapse PACS (7.5)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 3, 2025
Received: June 3, 2025

Dear Kulkarni Chaitrali:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243647

Device Name

Synapse PACS (7.5)

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.

FUJIFILM Synapse PACS Software provides toolsets for:

- Performing measurements on DICOM images
- Regional segmentation
- Importing and presenting data from modalities (DICOM and non-DICOM),
- Solving clinical calculations
- Creating and distributing structured reports

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, fusion, and volume rendering of studies to aid in reading, interpreting, reporting, and treatment planning.

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

MIP, MPR Fusion, and volume rendering are not intended for mammography use. FUJIFILM Synapse PACS Software can 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.

510(k) #: K243647

510(k) Summary

Prepared on: 2025-06-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Healthcare Americas Corporation
Applicant Address	81 Hartwell Ave Suite 300 Lexington MA 02421 United States
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Kulkarni Chaitrali
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Synapse PACS (7.5)
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190232	Synapse PACS	LLZ
K221677	Synapse 3D Base Tools v6.6	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

The Synapse PACS is an enterprise-wide medical information and image management software that runs on standard “off-the-shelf” PC hardware and Software (OS, browser). Synapse is intended for communication, storage, display, manipulation, measurement, printing, and processing of images and information acquired from various medical imaging and information systems. As a Software as a Medical Device (SaMD), Synapse PACS performs these purposes without being part of a hardware medical device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

FUJIFILM Synapse PACS Software provides toolsets for:

- Performing measurements on DICOM images
- Regional segmentation
- Importing and presenting data from modalities (DICOM and non-DICOM),
- Solving clinical calculations
- Creating and distributing structured reports

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, fusion, and volume rendering of studies to aid in reading, interpreting, reporting, and treatment planning.

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

MIP, MPR Fusion, and volume rendering are not intended for mammography use. FUJIFILM Synapse PACS Software can 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

There are no differences in the indication for use between the subject device and the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The differences between the features in the subject device and the primary predicate device are Volume Rendering Techniques, 3D Tools, Bone Removal, and 2-Point VOI. Although the primary predicate device does not have the features listed, the reference device have the same features. Because the predicate device and reference device contain the same features, the addition of the features in version 7.5 do not affect the safety or efficacy of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing result:

The differences between the features in the subject device and the primary predicate device are Volume Rendering Techniques including 3D Tools, 2-Point Volume of Interest (VOI), and Bone Removal.

The key addition to Synapse PACS 7.5.0 is the ability to perform volume rendering and 3D volume viewing for CT and MR.
The algorithm is already cleared and marketed for Synapse 3D (K221677, reference device). The volume rendering algorithms were integrated unchanged into Synapse PACS 7.5.0 (subject device).

The 2-point VOI performs is a semi-automatic segmentation of a lesion in CT and MRI images using the line drawn by the user on the lesion. The algorithm implemented is the same as already cleared and marketed algorithms for Synapse 3D (K221677, reference device). In Synapse3D, it is called Tumor Boundary Segmentation algorithm. The algorithm has been integrated into Synapse PACS unchanged compared to Synapse 3D. Comparison with Synapse 3D (K221677, reference device) provides the same results in Synapse PACS 7.5.0 (subject device).

Bone Removal is a tool that enhances the visibility of vessels in 3D rendered images by masking out bone regions. The tool is based on an AI algorithm cleared and marketed for Synapse 3D (K221677, reference device). It was improved for Synapse PACS 7.5.0. Comparison with Synapse 3D (K221677, reference device) showed that the improved algorithm does not affect the safety or efficacy of Synapse PACS 7.5.0 (subject device). Please refer to the Performance Bench Testing for testing with the improved algorithm.

Performance Testing Summary

A. Summary test statistics and acceptance criteria:

Dice Similarity Coefficient (DSC) and 95% Hausdorff Distance (HD) were used as primary and secondary endpoints to validate the performance of bone extraction algorithm. A pre-defined acceptance threshold of 0.951 was used for DSC. For 95% HD, we pre-define acceptance range 0.98 mm – 7.31 mm. The thresholds are determined after reviewing existing bone removal models in the literature.

The mean observed dice overlap coefficient and 95% HD with 95% confidence intervals were 0.959 [0.955 – 0.963] and 1.367 mm [1.170 mm – 1.563 mm], respectively, exceeding the predefined acceptance thresholds.

Across the subgroups— region, sex, age band, vendor, slice-thickness bin, body region, contrast—Dice values remained tightly clustered between 0.94 and 0.97 and 95 % HD never exceeded 2.57 mm. The 5 mm cohort shows a slightly lower Dice (0.942) because thick slices compress bone detail into fewer voxels, so tiny absolute deviations inflate the overlap metric; the boundary error remains modest (HD = 2.6 mm), confirming clinically acceptable performance.

B. The number of individual patient's images were collected from.

Images from 72 patients were collected, each patient had one image collected.

C. Demographic Distribution

Gender:
35 Males, 37 Females

Ages:
16 patients from ages 22-34
27 patients from ages 35-64
29 patients from ages 65-120

Regions:
20 patients from Midwest
20 patients from Southwest
32 patients from the Southeast

D. Information about image regions and confounders present in the dataset

Head/Neck: 16 images
Chest/Abdomen: 25 images
Abdomen/Pelvic: 19 images
Extremities: 6 images
Vascular/Others: 6 images

E. Information about equipment and protocols used to collect images

Images were collected from the following manufacturers:
28 SIEMENS, 22 GE, and 22 Philips

Slice thickness:

≤1.25mm: 29 images
1.25-2.5mm: 20 images
2.5-5.0mm: 23 images
≥5mm: 6 images

Contrast agent:
Contrast: 50 images
Non-contrast: 22 images

F. Information about how the reference standard was derived from the dataset (i.e., the "truthing" process)

An initial bone mask was created by certified technologist, then subjected to an independent dual-reader consensus review: two U.S. board-certified radiologists independently evaluated the mask, recorded any discrepancies, and iteratively reconciled them until consensus was achieved. The resulting consensus mask serves as the definitive ground truth for performance testing.