June 18, 2026

FUJIFILM Healthcare Americas Corporation
Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
81 Hartwell Ave.
Suite 100
Lexington, Massachusetts 02421

Re: K261713
Trade/Device Name: Synapse PACS (7.6.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 22, 2026
Received: May 22, 2026

Dear Chaitrali Kulkarni:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261713

Please provide the device trade name(s).

Synapse PACS (7.6.0)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261713

510(k) Summary

Prepared on: 2026-05-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Healthcare Americas Corporation
Applicant Address	81 Hartwell Ave Suite 100 Lexington MA 02421 United States
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Synapse PACS (7.6.0)
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
K243647	Synapse PACS (7.5.0)	QIH
K243762	Synapse 3D (7.0)	QIH

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)

There are no differences in features in the subject device and the primary predicate device.
The difference is in the implementation for Bone Removal and 2-point VOI.

- Bone Removal:Bone Removal in 7.5.0 was a Machine Learning algorithm. In 7.6.0 the algorithm was retrained to improve accuracy using additional data sets for the training.

- 2-point VOI:2-point VOI a non-ML algorithm was replaced by a Machine Learning algorithm originally cleared in Synapse 3D 7.0 (K243762), the reference device.

The implementation of Bone Removal and 2-point VOI do not raise any new concerns for the safety or efficacy of the subject device. The subject device is substantially equivalent to the predicate device.

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

Non-clinical testing result

The purpose of Product Development Process for Synapse PACS is to carry out the activities relating to the establishment of the Project Plan for conducting software hazard analysis, risk management, requirement analysis, architectural design, the design specification, unit implementation and verification, software integration and integration testing, software system test, software release, software maintenance.
The main activities in the software development process are described as follows.
• Software development plan (Project Plan)
• Software hazard analysis and risk management
• Software requirements analysis/specification
• Software architectural design
• Software detailed design specification
• Software unit module implementation and verification
• Software integration and system testing

Verification and Validation
Verification and Validation was performed in accordance with the MI Product Development Process.

Verification
The features and functions of Synapse 7.6.000 have been verified against the Software Verification Test Protocol to operate correctly using supported hardware/software configurations of Synapse 7.6.000. No open issues are classified as Major severity or Critical severity that would prevent the release of this software version. Test Protocols, Test Runs, Test Reports and Traceability Matrix are provided as part of this submission.

Validation
The features and functions of Synapse 7.6.000 have been validated against the Design Validation Test Protocol. Tests were executed by Product Owners and have been validated to operate correctly using supported hardware/software configurations of Synapse 7.6.000. No open issues are classified as Major severity or Critical severity that would prevent the release of this software version. Test Protocols, Test

Runs, Test Reports and Traceability Matrix are provided as part of this submission.

Performance Testing Summary

(A) Summary test statistics and acceptance criteria:
Dice Similarity Coefficient (DSC) and 95% Hausdorff Distance (HD95) were used as primary and secondary endpoints to validate the performance of Bone Extraction and 2-Point VOI algorithms to establish non-inferiority with predicate and reference device.
The pre-defined acceptance criteria for each of the endpoints are:

i) Dice Acceptance: The 95% Confidence Interval (CI) lower bound of the Subject–Predicate difference must be > -0.05 (representing a 5% tolerance).
ii) HD95 Acceptance: The 95% CI upper bound of the Subject – Predicate difference must be less than the respective physical scanner resolution limits. specifically, 2.11 mm for Bone Extraction, 2.371 mm for 2P VOI (CT), and 3.413mm for 2P VOI (MRI)

Both the algorithms met the pre-specified acceptance criteria for non-inferiority. The Bone Removal algorithm achieved a mean Dice of 0.963, and the 2-Point VOI algorithm achieved mean Dice scores of 0.850 for CT and 0.756 for MRI.

(B) The number of individual patient images collected from.
Validation was conducted on independent, sequestered U.S. clinical datasets that were entirely separate from all training and internal tuning data. The Bone Removal algorithm was tested using 72 individual patient cases. The 2-Point VOI algorithm was validated using a total of 162 patient cases, which included 29 cases for the CT modality and 133 cases for the MRI modality

(C) Demographic Distribution Gender:
The validation datasets represented a diverse demographic and geographic cross-section of the United States. For Bone Removal, the study included 35 male and 37 female subjects across age groups ranging from 22 to 120 years, with patients sourced from the Mid-west (20), South-west (20), and South-east (32) regions. For 2-Point VOI (combined CT and MRI), the study included 116 male and 46 female subjects, with ages also ranging from 22 to 120 years. These cases were sourced broadly across the East (75), South-east (48), Mid-west (37), and South-west (2) regions

(D) Information about image regions and confounders present in the dataset
The study included a wide range of anatomical regions and clinical confounders to ensure real-world robustness. For Bone Removal, the 72-case dataset included 16 head/neck, 25 chest/abdomen, 19 abdomen/pelvic, and 12 extremities/other images. Potential confounders tested included contrast agent usage (50 contrast, 22 non-contrast) and radiation dose (53 normal, 19 low dose). For 2-Point VOI, the 162-case dataset included 11 brain/head, 14 chest, 38 abdomen/pelvis/liver/kidney/pancreas, and 99 prostate/rectum/other/whole body images. Confounders included varying contrast usage, radiation dose levels for CT, and magnetic field strengths (1.0T, 1.5T, and 3.0T) for MRI.

(E) Information about equipment and protocols used to collect images
Images were sourced from major manufacturers to demonstrate hardware-agnostic performance. For Bone Removal, cases were collected from 28 Siemens, 22 GE, and 22 Philips scanners. Slice thickness distribution included 29 images at ≤1.25 mm, 20 at 1.25–2.5 mm, 17 at 2.5–5.0 mm, and 6 at ≥5 mm. For 2-Point VOI, images were sourced from 90 Siemens, 33 GE, and 39 Philips scanners. Slice thickness distribution for this group included 21 images at ≤1.25 mm, 12 at 1.25–2.5 mm, 122 at 2.5–5.0 mm, and 7 at ≥5 mm

(F) Information about how the reference standard was derived from the dataset (i.e., the “truthing” process)
An initial draft 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.

Risk Analysis
Risk Analysis was performed. The review did not identify any foreseeable hazards, and the risk management plan is effective. No intolerable Risks exist. The overall residual risk is acceptable. The Overall residual risk is acceptable. The Benefits for this device outweigh the Risks. The Risk Management files are provided as part of this submission.