May 21, 2025

FUJIFILM Corporation
Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
26-30, Nishiazabu 2-Chome
Minato-ku, Tokyo 106-8620
Japan

Re: K243762
Trade/Device Name: Synapse 3D Base Tools (V7.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 25, 2025
Received: April 25, 2025

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 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,

for

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

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)*

K243762

Device Name

Synapse 3D Base Tools (V7.0)

Indications for Use *(Describe)*

Synapse 3D Base Tools is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Base Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, CR, US, NM, PT, and XA, etc.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. Synapse 3D Base Tools provides several levels of tools to the user: Basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), Maximum (MIP), Average (RaySum) and Minimum (MinIP) Intensity Projection, 4D volume viewing, image fusion, image subtraction, surface rendering, sector and rectangular shape MPR image viewing, MPR for dental images, creating and displaying multiple MPR images along an object, time-density distribution, basic image processing, noise reduction, CINE, measurements, annotations, reporting, printing, storing, distribution, and general image management and administration tools, etc.

• Tools for regional segmentation of anatomical structures within the image data, path definition through vascular and other tubular structures, and boundary detection.
• Image viewing tools for modality specific images, including CT PET fusion and ADC image viewing for MR studies.
• Imaging tools for CT images including virtual endoscopic viewing, dual energy image viewing.
• Imaging tools for MR images including delayed enhancement image viewing, diffusion-weighted MRI image viewing.

The intended patient population for all applications implemented as base tools is limited to adult population (over 22 years old).

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) Summary

Date Prepared:	May 19th, 2025
Submitter's Information:	FUJIFILM Corporation 26-30 NISHIAZABU, 2-CHOME MINATO-KU, TOKYO 106-8620
Contact Person:	Chaitrali Kulkarni Senior Regulatory Affairs Specialist Telephone: (704) 517-4886 Email: chaitrali.kulkarni@fujifilm.com
Device Trade Name:	Synapse 3D Base Tools V7.0
Device Common Names:	Automated radiological image processing software
Device Classification Name:	System, Image Processing, Radiological
Product Code:	QIH, LLZ
Regulation Number:	21 CFR 892.2050
Device Class:	Class II
Panel:	Radiology
Predicate Devices:	Synapse 3D Base Tools V6.6 (K221677) FUJIFILM Corporation

1. Description of the Device

Synapse 3D Base Tools (V7.0) (this submission) is updated software of previously-cleared Synapse 3D Base Tools (V6.6) (cleared by CDRH via K221677 on 11/10/2022).

The 3D image analysis software Synapse 3D Base Tools (V7.0) is medical application software running on Windows server/client configuration installed on commercial general-purpose Windows-compatible computers. It offers software tools which can be used by trained professionals to interpret medical images obtained from various medical devices, to create reports, or to develop treatment plans.

Synapse 3D Base Tools is connected through DICOM standard to medical devices such as CT, MR, CR, US, NM, PT, XA, etc. and to a PACS system storing data generated by these medical devices, and it retrieves image data via network communications based on the DICOM standard. The retrieved image data are stored on the local disk managed by Synapse 3D Base Tools (V7.0), and the associated image-related information of the image data is registered in its database and is used for display, image processing, analysis, etc. Images newly created by Synapse 3D Base Tools (V7.0) not only can be displayed on a display, but also can be printed on a hardcopy using a DICOM printer or a Windows printer.

Synapse 3D Base Tools (V7.0) is a basic software module that works with other cleared clinical applications, including Synapse 3D Cardiac Tools (K200973), Synapse 3D Perfusion Analysis (K162287), Synapse 3D Lung and Abdomen Analysis (K130542), Synapse 3D Liver and Kidney Analysis (K142521), Synapse 3D Nodule Analysis (K120679), Synapse 3D Colon Analysis (K123566), Synapse 3D Tensor Analysis (K141514) and Synapse 3D Blood Flow Analysis (K191544). All these software modules consist of the Synapse 3D product family.

Synapse 3D Base Tools can be integrated with Fujifilm's Synapse PACS, and can be used as a part of a Synapse system. Synapse 3D Base Tools also can be integrated with Fujifilm's Synapse Cardiovascular for cardiology purposes.

2. Indications for Use

Synapse 3D Base Tools is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Base Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, CR, US, NM, PT, and XA, etc.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Synapse 3D Base Tools provides several levels of tools to the user:

Basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), Maximum (MIP), Average (RaySum) and Minimum (MinIP) Intensity Projection, 4D volume viewing, image fusion, image subtraction, surface rendering, sector and rectangular shape MPR image viewing, MPR for dental images, creating and displaying multiple MPR images along an object, time-density distribution, basic image processing, noise reduction, CINE, measurements, annotations, reporting, printing, storing, distribution, and general image management and administration tools, etc.

- Tools for regional segmentation of anatomical structures within the image data, path definition through vascular and other tubular structures and boundary detection.
- Image viewing tools for modality specific images, including CT PET fusion, ADC image viewing for MR studies.
- Imaging tools for CT images including virtual endoscopic viewing and dual energy image viewing.
- Imaging tools for MR images including delayed enhancement image viewing, diffusion-weighted MRI image viewing.

The intended patient population for all applications implemented as base tools is limited to adult population (over 22 years old).

3. Substantial Equivalence Comparison

Synapse 3D Base Tools has the same intended use, similar labeling, and clinical application tools as those of the cleared predicate device Synapse 3D Base Tools V6.6 (K221677). The device features and technical characteristics comparison with predicates is shown as **Table 1** Device Features and Technical Characteristics Comparison Matrix.

Table 1 Device Features and Technical Characteristics Comparison Matrix

Device Parameters	**Synapse 3D Base Tools (V7.0) (This submission)**	**Synapse 3D Base Tools(V6.6) (K221677) (Primary predicate device)**	**Comparison**
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulatory Number	892.2050	892.2050	Same
Product Code	QIH, LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same
Decision Date	-	November 10, 2022	Predicate device is cleared
2D Viewing	Yes	Yes	Same
Image Storing (DICOM SCP)	Yes	Yes	Same
Image Communication (DICOM SCU)	Yes	Yes	Same
DICOM Interface (SCP/SCU)	Yes	Yes	Same
Printing (DICOM SCU)	Yes	Yes	Same
Measurements (2D and 3D)	Yes	Yes	Same
Annotations - Standardized and Free Text	Yes	Yes	Same
Reporting	Yes	Yes	Same
Cine	Yes	Yes	Same

Device Parameters	Synapse 3D Base Tools (V7.0) (This submission)	Synapse 3D Base Tools(V6.6) (K221677) (Primary predicate device)	Comparison
Volume Rendering and 3D Viewing	Yes	Yes	Same
MPR ▪ orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), ▪ Sector and rectangular shape MPR image viewing ▪ MPR for dental images ▪ Multiple MPR images along an object (Slicer)	Yes	Yes	Same
Maximum, Average, Minimum Intensity Projection	Yes	Yes	Same
4D viewing	Yes	Yes	Same
Image fusion	Yes	Yes	Same
Surface rendering	Yes	Yes	Same
Image subtraction (3D)	Yes	Yes	Same
Time-density distribution	Yes	Yes	Same

Device Parameters	Synapse 3D Base Tools (V7.0) (This submission)	Synapse 3D Base Tools(V6.6) (K221677) (Primary predicate device)	Comparison
General image data management and administration tools	Yes	Yes	Same
Segmentation	Yes	Yes	Some new segmentation applications are added and implemented using the same deep learning method called as “Fully Convolutional Network”.
Path definition	Yes	Yes	Same
Boundary detection	Yes	Yes	Same
CT PET fusion	Yes	Yes	Same
ADC image viewing (MRI)	Yes	Yes	Same
Virtual Endoscopic Simulator	Yes	Yes	Same
Diffusion-weighted MRI Data Analysis	Yes	Yes	Same
Delayed Enhancement Image Viewing	Yes	Yes	Same
Dual Energy image viewing	Yes	Yes	Same
PixelShine	Yes	Yes	Same
Pancreas Analysis	Yes	No	Added new feature. Note: The new feature

Device Parameters	Synapse 3D Base Tools (V7.0) (This submission)	Synapse 3D Base Tools(V6.6) (K221677) (Primary predicate device)	Comparison
			Pancreas Analysis is the similar to Contour ProtégéAI ("Reference Device"), which was cleared by CDRH via K213976 on 02/03/2022. This added new feature does not raise different questions of safety and effectiveness.
Rectal Analysis	Yes	No	Added new feature. Note: The new feature Rectal Analysis is the similar to Contour ProtégéAI ("Reference Device"), which was cleared by CDRH via K213976 on 02/03/2022. This added new feature does not raise different questions of safety and effectiveness.
Segmentation Viewer	Yes	No	Added new feature. Note: The new feature Segmentation Tools is the similar to Contour ProtégéAI ("Reference Device"), which was cleared by CDRH via K213976 on 02/03/2022. This added new feature does not

Device Parameters	Synapse 3D Base Tools (V7.0) (This submission)	Synapse 3D Base Tools(V6.6) (K221677) (Primary predicate device)	Comparison
			raise different questions of safety and effectiveness.
Post-reconstruction request	Yes	No	Added new feature. Note: The new feature Post-reconstruction request is the same as the feature available on the SCENARIA View ("Reference Device"), which was cleared by CDRH via K190841 on 09/13/2019. This added new feature does not raise different questions of safety and effectiveness.
Spatial reproduction display	Yes	No	Added new feature. Note: The purpose of this function is the visualization of organs, etc. Therefore, this added feature does not raise different questions of safety and effectiveness.
Product Availability	Software Product	Software Product	Same
Hardware Platform	Windows PC	Windows PC	Same

4. Safety Information

Synapse 3D Base Tools introduces no new safety or efficacy issues other than those already identified with the predicate devices. As part of the Risk Management process, appropriate preventive measures in response to the results of the Hazard Analysis have been taken in accordance with the June 14, 2023 issue of the "*Guidance for the Content of Premarket Submissions for Device Software Functions*." The Synapse 3D Base Tools 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

Nonclinical testing result:

The purpose of Software Development Process for Synapse 3D Base Tools is to carry out the activities relating to the establishment of the software development plan (or plans) for definitely 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 software development process are described as follows.

- Software development 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

Clinical tests:

The subject of this 510(k) notification, Synapse 3D Base Tools does not require clinical studies to support safety and effectiveness of the software.

Verification and Validation:

Testing for verification and validation 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, benchmark performance testing was conducted using actual clinical images to help demonstrate that the semi-automatic or automatic segmentation, detection, and registration functions implemented in Synapse 3D Base Tools 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 passed successfully according to the design specifications. All of the different components of the Synapse 3D Base Tools software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate according to its intended use and in a manner substantially equivalent to the predicate devices.

For the automatic or semi-automatic organ extraction functions constructed using deep learning, the performance testing was conducted using the test data that are independence from training data. A total of 1086 cases of US patient population were collected newly from the following regions for the performance testing.

Region	**Number of cases**
US_East	295
US_Midwest	175
US_Southeast	185
US_Southwest	73
US_Nouthwest	4

The information about the dataset for the performance testing as shown in details in the following table.

Items	**Subitems**	**Number of cases**
Total		1086
Sex	Men	672
	Women	414
Age	22-34 years old	23
	35-64 years old	484
	65-120 years old	579
Manufacturer	SIEMENS	507
	GE	288
	PHILIPS	260
	CANON(TOSHIBA)	22
	FUJIFILM(HITACHI)	9
SliceThickness	0.0-0.99mm	86
	1.0-1.24mm	134
	1.25-1.49mm	49
	1.5-1.99mm	6
	2.0-2.49mm	91
	2.5-2.99mm	56
	3.0-3.99mm	450
	4.0-4.99mm	121
	⩾5.0	93

The dataset shown as above was used for the performance testing, the results was summarized as follows.

	Number of cases	DICE (Average)
Duodenum (CT)	30	0.85
Stomach (CT)	30	0.96
Lung section (Left S1S2) (CT)	30	0.92
Lung section (Left S3) (CT)	30	0.88
Lung section (Left S4) (CT)	30	0.75
Lung section (Left S5) (CT)	30	0.81
Lung section (Left S6) (CT)	30	0.9
Lung section (Left S8) (CT)	30	0.85
Lung section (Left S9) (CT)	30	0.73
Lung section (Left S10) (CT)	30	0.87
Lung section (Right S1) (CT)	30	0.89
Lung section (Right S2) (CT)	30	0.89
Lung section (Right S3) (CT)	30	0.91
Lung section (Right S4) (CT)	30	0.88
Lung section (Right S5) (CT)	30	0.85
Lung section (Right S6) (CT)	30	0.9
Lung section (Right S7) (CT)	30	0.8
Lung section (Right S8) (CT)	30	0.84
Lung section (Right S9) (CT)	30	0.71
Lung section (Right S10) (CT)	30	0.83
Pancreas section (Body) (CT)	29	0.91
Pancreas section (Head) (CT)	29	0.95
Pancreas section (Tail) (CT)	29	0.99
Spleen (CT)	35	0.95
Pancreas duct (CT)	29	0.74
Pancreas (CT)	30	0.86
ROI (CT)*	29	0.85
Liver section (S1) (CT)	31	0.99
Liver section (S2) (CT)	31	0.99
Liver section (S3) (CT)	31	0.97
Liver section (S4) (CT)	31	0.97
Liver section (S5) (CT)	31	0.92

Liver section (S6) (CT)	31	0.94
Liver section (S7) (CT)	31	0.98
Liver section (S8) (CT)	31	0.97
Gall bladder (CT)	37	0.92
Bronchus (CT)	30	0.87
Lung lobe (Left Lower) (CT)	30	0.99
Lung lobe (Left Upper) (CT)	30	0.99
Lung lobe (Right Lower) (CT)	30	0.99
Lung lobe (Right Middle) (CT)	30	0.97
Lung lobe (Right Upper) (CT)	30	0.99
Pulmonary Arteries (CT)	30	0.83
Pulmonary Veins (CT)	30	0.85
Pancreas vessel (CT)	30	0.9

	Number of cases	**DICE (Average)**
Prostate (MRI)	30	0.9
Rectal ROI (tumor) (MRI)*	27	0.75
Ureter (T2) (MRI)	33	0.63
Bladder (MRI)	35	0.93
Pelvis (MRI)	34	0.94
Seminal vesicle (MRI)	32	0.7
Ureter (T1Dynamic) (MRI)	33	0.76
Prostate tumor (DWI) (MRI)*	36	0.65
Prostate tumor (T2) (MRI)*	39	0.6
Kidney tumor (MRI)*	31	0.88
Left Kidney (MRI)	31	0.97
Right Kidney (MRI)	31	0.98
ROI (MRI)*	133	0.72
Rectal muscularis propria (MRI)	32	0.91
Mesorectum (MRI)	32	0.9
Pelvic vessel (Artery) (MRI)	30	0.81
Pelvic vessel (Vein) (MRI)	30	0.8
Kidney vessel (Artery) (MRI)	32	0.92
Kidney vessel (Vein) (MRI)	32	0.86
Pelvic nerve (MRI)	30	0.7

Levator ani muscle (MRI)	30	0.77

*Here, this extraction is performed semi-automatically. All other extraction functions are executed automatically. Additional distance based metrics 95% Hausdorff Distance and Mean Surface Distance were also reported along with the subgroup analysis. Detailed results are reported in the labeling.

Cybersecurity:

The confidentiality, integrity and availability are maintained by Synapse 3D Base Tools in accordance with **Section IV (B.)** of the *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (April 8, 2022)*.

Synapse 3D Base Tools is connected through DICOM standard to medical devices and to a PACS system storing data generated by these medical devices, and it retrieves image data via network communication based on the DICOM standard. Therefore Synapse 3D Base Tools assures an adequate degree of protection for cybersecurity.

Performance standards:

- *Digital Imaging and Communications in Medicine (DICOM) Set (PS 3.1 – 3.20) (2016).*
- *IEC 62304 Edition 1.1 2015-06, Medical Device Software - Software Life Cycle Processes.*
- *ISO 14971:2019 2019-12-10, Medical Devices - Application of Risk Management to Medical Devices.*

6. Conclusion

Performance tests were conducted to test the functionality of the subject device, Synapse 3D Base Tools. Results of all conducted testing were acceptable in supporting the claim of substantial equivalence.