April 30, 2026

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

Re: K254189
Trade/Device Name: Synapse 3D Base Tools (V7.2)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: March 30, 2026
Received: March 31, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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.

510(k) Number *(if known)*
K254189

Device Name
Synapse 3D Base Tools (V7.2)

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.
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 Intensity Projection (MIP), Average Intensity Projection (RaySum) and Minimum Intensity Projection (MinIP), 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.
- Regional segmentation tools for anatomical structures within image data, including path definition through vascular and other tubular structures and boundary detection.
- Modality-specific image viewing tools, including fusion and ADC image viewing for MR studies.
- General imaging tools for CT images, including virtual endoscopic viewing, dual energy image viewing, and segmentation of ROI based on user-specified locations.
- General imaging tools for MR images, including diffusion-weighted MRI viewing.
- Cardiac analysis for MR heart images, including delayed enhancement image viewing, functional characteristics viewing, and calcium scoring.
- Blood flow analysis for multi-phase and velocity-encoded MR images, including blood flow velocity and direction analysis.
- Lung analysis for non-contrast and contrast-enhanced CT images, including boundary detection and volume calculation for pulmonary nodules based on user-specified locations, segmentation of bronchial tubes, approximation of air supply regions by user-defined bronchial tubes, identification and processing of low absorption regions, analysis of bronchial pathways to reach lung nodules using CT volume data, and simulation of bronchoscope insertion along the path.
- Liver analysis for contrast-enhanced CT images, including liver and peripheral organ segmentation, tumor segmentation based on user-specified locations, segmentation of intrahepatic and peripheral vessels, and approximation of vascular territories.
- Tensor analysis for neck and head MR images, including diffusion and FA color maps, white matter tractography, dynamic MR review, and vessel and body visualization with registration of MR, CT, XA, PET, and NM.
- Perfusion analysis for dynamically scanned cerebral CT arteriography, including parameters such as blood volume (BV), blood flow (BF), mean transit time (MTT), and time to peak (TTP).

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

Date Prepared:	December 23, 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: HCUSRegulatoryAffairs@fujifilm.com
Device Trade Name:	Synapse 3D Base Tools (V7.2)
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 (V7.0) (K243762) FUJIFILM Corporation

1. Description of the Device

Synapse 3D Base Tools (V7.2) (this submission) is updated software of previously-cleared Synapse 3D Base Tools (V7.0) (cleared by CDRH via K243762 on 05/21/2025).

The 3D image analysis software Synapse 3D Base Tools (V7.2) 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 (V7.2) is connected through DICOM standard to medical devices such as CT, MR, CR, US, NM, PT, and 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 (V7.2), 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 (V7.2) 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 (V7.2) 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 (V7.2) 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. Intended Patient Population

The intended patient population for all applications implemented is limited to adults aged 22 years and older.

3. 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.

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 Intensity Projection (MIP), Average Intensity Projection (RaySum) and Minimum Intensity Projection (MinIP), 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.
- Regional segmentation tools for anatomical structures within image data, including path definition through vascular and other tubular structures and boundary detection.
- Modality-specific image viewing tools, including fusion and ADC image viewing for MR studies.
- General imaging tools for CT images, including virtual endoscopic viewing, dual energy image viewing, and segmentation of ROI based on user-specified locations.
- General imaging tools for MR images, including diffusion-weighted MRI viewing.
- Cardiac analysis for MR heart images, including delayed enhancement image viewing, functional characteristics viewing, and calcium scoring.
- Blood flow analysis for multi-phase and velocity-encoded MR images, including blood flow velocity and direction analysis.
- Lung analysis for non-contrast and contrast-enhanced CT images, including boundary detection and volume calculation for pulmonary nodules based on user-specified locations, segmentation of bronchial tubes, approximation of air supply regions by user-defined bronchial tubes, identification and processing of low absorption regions, analysis of bronchial pathways to reach lung nodules using CT volume data, and simulation of bronchoscope insertion along the path.
- Liver analysis for contrast-enhanced CT images, including liver and peripheral organ segmentation, tumor segmentation based on user-specified locations, segmentation of intrahepatic and peripheral vessels, and approximation of vascular territories.
- Tensor analysis for neck and head MR images, including diffusion and FA color maps, white matter tractography, dynamic MR review, and vessel and body visualization with

registration of MR, CT, XA, PET, and NM.
- Perfusion analysis for dynamically scanned cerebral CT arteriography, including parameters such as blood volume (BV), blood flow (BF), mean transit time (MTT), and time to peak (TTP).

4. Comparison

Because Synapse 3D Base Tools (V7.2) (this submission) is updated software of previously-cleared Synapse 3D Base Tools (V7.0) (cleared by CDRH via K243762 on 05/21/2025), the Synapse 3D Base Tools (V7.0) (K243762) is used as predicate device and the other reference devices are listed in the following **Table 1**.

Table 1 The predicate device and reference devices

Predicates	Device name	Medical Specialty	Regulation	Product code
Predicate device	**Synapse 3D Base Tools (V7.0) (K243762)**	**Radiology**	**892.2050 - Medical image management and processing system**	**QIH (Class 2) - Automated Radiological Image Processing Software LLZ (Class 2) - System, Image Processing, Radiological**
Reference devices	NeuroQuant (K170981)	Radiology	892.2050 - Medical image management and processing system	LLZ (Class 2) - System, Image Processing, Radiological
	Synapse 3D Cardiac Tools (K200973)	Radiology	892.2050 - Medical image management and processing system	LLZ (Class 2) - System, Image Processing, Radiological
	Synapse 3D Blood	Radiology	892.2050 - Medical	LLZ (Class 2) - System,

	Flow Analysis (K191544)		image management and processing system	Image Processing, Radiological
	Synapse 3D Lung and Abdomen Analysis (K130542)	Radiology	892.2050 - Medical image management and processing system	LLZ (Class 2) - System, Image Processing, Radiological
	Synapse 3D Liver and Kidney Analysis (K142521)	Radiology	892.2050 - Medical image management and processing system	LLZ (Class 2) - System, Image Processing, Radiological
	Synapse 3D Tensor Analysis (K141514)	Radiology	892.2050 - Medical image management and processing system	LLZ (Class 2) - System, Image Processing, Radiological
	Synapse 3D Perfusion Analysis (K162287)	Radiology	892.2050 - Medical image management and processing system	LLZ (Class 2) - System, Image Processing, Radiological

The following tools are the new features in this device.

Application Name

- Brain Subregion Analysis

  Brain Subregion Analysis extracts a subregion of the brain and calculates the

volume of this region. This can be compared to past results to observe changes in volume over time.

In 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, arbitrary regions can be extracted manually for 3D observation, volume measurement, and the comparison with past data can be performed. The differences between the new feature Brain Subregion Analysis and Predicate Device are that the automatic extraction of brain subregions are performed for brain subregion analysis.

The new feature Brain Subregion Analysis is similar to Contour NeuroQuant ("Reference Device"), which was cleared by CDRH via K170981on 09/07/2017. Brain subregion segmentation accuracy in Brain Subregion Analysis compared to expert manual segmentations was evaluated using Dice's coefficient metric and the Dice's coefficients were obtained in the range of 80-90%, the mean percentage absolute volume differences were in the range1-5%. This added new feature does not raise different questions of safety and effectiveness.

- CSF Space Analysis

CSF Space Analysis extracts the high-convexity SAS (SAS(Upper)), Sylvian fissure and basal cistern (SAS(Lower)), and brain ventricle, and calculates data such as the volume of these regions.

In 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, arbitrary regions can be extracted manually for 3D observation, volume measurement. The differences between the applied function's CSF Space Analysis and Predicate Device are that the automatic extraction of high-convexity SAS (SAS(Upper)), Sylvian fissure and basal cistern (SAS(Lower)) and brain ventricle can be performed for CSF Space Analysis. The new feature Brain Subregion Analysis is similar to Contour NeuroQuant ("Reference Device"), which was cleared by CDRH via K170981on 09/07/2017. The segmentation accuracy of brain regions in CSF Space Analysis such as the high-convexity SAS (SAS(Upper)), Sylvian fissure and basal cistern (SAS(Lower)), and brain ventricle compared to expert manual segmentations was evaluated using Dice's coefficient metric and the Dice's coefficients were obtained in the range of 80-90%, the mean percentage absolute volume differences were in the range1-5%. This added new feature does not raise different questions of safety and effectiveness.

- Interventional Radiology Simulator

Interventional Radiology simulator enables preliminary Interventional Radiology simulation by extracting target regions and paths up to the target regions such as tumors or lesions.

In the CPR Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, blood vessel can be extracted and setting of the shortest path to the target location can be performed manually. The differences between the new application Interventional Radiology Simulator application and Predicate Device are that the semi-automatic extraction of blood vessels, semi-automatic extraction of tumor regions and the setting of shortest path to the target location can be performed for new application Interventional Radiology Simulator. The semi-automatic extraction performance for

blood vessels meets the acceptance criteria, and the semi-automatic extraction accuracy for tumor regions has demonstrated effectiveness in SYNAPSE 3D Base Tools(V7.0) (K243762). Therefore, the differences do not raise different questions of safety and effectiveness.

- Cardiac Function MR

Cardiac Function MR is an application for cardiac function evaluation that obtains ventricle and myocardium boundaries from MR images consisting of multiple time phases and calculates ejection fraction, end-diastolic volume, end-systolic volume, stroke volume, and other information.

In the 4D Viewer Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, arbitrary regions can be extracted manually for 3D observation, measure volume, and 3D cine playback. Meanwhile, the Cardiac Function MR application automatically extracts the right ventricle, left ventricle, and left ventricular myocardium, providing functions for 3D observation, volume measurement, 3D cine playback, and calculation of analytical values such as cardiac ejection fraction from time-series data.

The differences between this new application Cardiac Function MR and the Predicate Device are that the automatic extraction of the right ventricle, left ventricle, and left ventricular myocardium, and the ability to calculate analytical values such as ejection fraction from time-series data can be performed for new application Cardiac Function MR. Here, it was confirmed that the performance of automatic extraction used in this application meets the acceptance criteria.
Furthermore, except for the strain analysis, the inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Cardiac Tools ("Reference Device"), which was cleared by CDRH via K200973 on 08/27/2020.
The quantitative validity of the strain analysis have also been confirmed.
This added new feature does not raise different questions of safety and effectiveness.

- Calcium Scoring

Calcium Scoring displays the plaque area of the coronary artery by color, and calculates the quantitative value of plaque by using the Agatston score method.

In the 3D Viewer Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, any region can be extracted manually and perivascular fat around the region can be extracted using thresholding. The difference between the new application Calcium Scoring and the Predicate Device are that the automatic extraction of the heart and extraction of surrounding fat using thresholding. Since the performance of the automatic extraction used in the application meets the qualification criteria, it has been confirmed that the differences do not affect its validity.
The inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Cardiac Tools ("Reference Device"), which was cleared by CDRH via K200973 on 08/27/2020.
This added new feature does not raise different questions of safety and

effectiveness.

- 4D Flow

In 4D Flow, the flow volume and flow velocity for an arranged ROI can be calculated.

In the 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, blood vessels can be extracted manually. The difference between the new application 4D Flow and the Predicate Device are that semi-automatic extraction of blood vessels and calculation of analytical values such as 3D blood flow from multiple MRI images can be performed for new application 4D Flow. The performance of semi-automatic extraction meets the acceptance criteria.
Except for the Q-value and vorticity, the inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Blood Flow Analysis ("Reference Device"), which was cleared by CDRH via K191544 on 10/18/2019.
The quantitative validity of Q-value and vorticity have also been confirmed.
This added new feature does not raise different questions of safety and effectiveness.

- Lung Analysis/Airway

In Lung Analysis/Airway, the various types of analysis for lung nodules, bronchi, lower attenuation areas, etc. can be performed using the volume data collected by CT.

In the 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, any region of interest (ROI) can be extracted manually. The difference between the new application Lung Analysis/Airway and the Predicate Device are that the automatic extraction of lung fields, semi-automatically extraction of nodules, and cluster analysis and display statistical measures can be performed for new application Lung Analysis/Airway. The accuracy of the automatic lung field extraction in the submitted function meets the qualification criteria. The accuracy of the semi-automatic nodule extraction has been demonstrated to be effective in Synapse 3D Base Tools (V7.0) **(**K243762**)**. Furthermore, except for the quantitative measurement named PD15, the inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Lung and Abdomen Analysis ("Reference Device"), which was cleared by CDRH via K130542 on 06/14/2013.
The quantitative validity of PD15 have also been confirmed.
This added new feature does not raise different questions of safety and effectiveness.

- Liver Analysis

Liver Analysis extracts the liver and nearby vessel regions from contrast-enhanced CT or MR images and displays the results as 3D images. In addition, the dominant region of the extracted liver region, portal vein, and veins can be extracted and divided into areas, and a hepatectomy simulation can be performed.

In the 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, any region of interest (ROI) can be extracted manually. The difference between the new application Liver Analysis and the Predicate Device are that the automatic

extraction of the liver and blood vessels and calculation of the territory. The extraction accuracy of the liver and blood vessels in the application meets the acceptance criteria, and the inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Liver and Kidney Analysis (“Reference Device”), which was cleared by CDRH via K142521 on 12/01/2014. This added new feature does not raise different questions of safety and effectiveness.

- Craniotomy/tensor Analysis

In craniotomy/tensor analysis, tensor analysis is performed on MR diffusion-weighted images to extract and visualize nerve fiber pathways using tractography. By primarily loading CT images and extracting bone, brain parenchyma, tumors, and cranial vessels, craniotomy procedures can be simulated.

In the 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, any region of interest (ROI) can be extracted manually. The differences between the Craniotomy/Tensor Analysis application feature and the Predicate Device are: the ability to automatically extract bone, brain parenchyma, tumor, artery, and vein; the ability to display FA images and diffusion color maps; and the ability to perform tensor analysis assuming free diffusion and DKI analysis assuming restricted diffusion. The Craniotomy/Tensor Analysis application feature's automatic extraction of bone, brain parenchyma, tumor, arteries, and veins meet the acceptance criteria. Furthermore, except for the DKI analysis, the inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Tensor Analysis (“Reference Device”), which was cleared by CDRH via K141514 on 09/06/2014.
The quantitative validity of the DKI analysis have been confirmed.
Therefore, it has been confirmed that the differences do not affect the validity and do not raise different questions of safety and effectiveness.

- Brain Perfusion CT

Brain Perfusion CT analyzes the changes in cerebral blood flow from the dynamic scan images of CT for the same slice and calculates CBV (cerebral blood volume), CBF (cerebral blood flow), MTT (mean transient time), TTP (time-to-peak of the contrast medium), and Tmax (time-to-peak of the residual function) from the analysis results. Brain Perfusion CT is an application only for CT. This application does not support images of other modalities.

In the 3D viewer application of the Predicate Device, SYNAPSE 3D Base Tools (V7.0) **(**K243762**)**, any region of interest (ROI) can be extracted manually. The differences between the Brain Perfusion CT feature in the subject device and the Predicate Device are the ability to automatically extract the brain and the ability to display diffusion-related quantitative maps. The automatic brain extraction in the subject device meets the acceptance criteria, and the inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Perfusion Analysis (“Reference Device”), which was cleared by CDRH via K162287 on 04/06/2017; therefore, these differences do not affect effectiveness.

- Flow Analysis

In MR flow analysis, the flow velocity and flow volume per heart rate of an arranged ROI can be calculated.

In the 3D viewer application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, blood vessels can be extracted manually. The difference between the new application Flow Analysis and the Predicate Device are that the semi-automatic extraction of blood vessels and calculation of analytical values such as 2D blood flow from multiple MRI images can be performed for the new application Flow Analysis. The semi-automatic extraction performance used in this application meets the acceptance criteria. The inputs/outputs, and underlying algorithm are the same as those of Synapse 3D Blood Flow Analysis ("Reference Device"), which was cleared by CDRH via K191544. It has been confirmed that the differences do not affect the validity and do not raise different questions of safety and effectiveness.

- Delayed Enhanced

Delayed Enhancement accepts delayed enhancement MR images, extracts enhanced regions (high-signal value regions) in heart from 2D or 3D images with the preset threshold value, calculates the area of the enhanced regions and displays in bull's eye, and calculates the volume.

In the Delayed Enhanced Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, cardiac LV and myocardium can be extracted manually. The differences between the new application and Predicate Device are that the automatic extraction of cardiac LV and myocardium. The automatic extraction performance meets the acceptance criteria. Therefore, the differences do not raise different questions of safety and effectiveness.

- Segmentation Viewer

In segmentation Viewer, it is possible to automatically extract the surrounding tissues of the lung/liver/pancreas from contrast-enhanced CT scans, and extract ROIs semi-automatically from MR images of the kidney/rectum/prostate, allowing them to be used for preoperative simulation of tumor resection.

In the Segmentation Viewer Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, periprostatic tissue (MRI), Vagina (MRI), and cervix (MRI) can be extracted manually. The differences between the new application and Predicate Device are that the automatic extraction of periprostatic tissue (MRI), Vagina (MRI), and cervix (MRI). The automatic extraction performance meets the acceptance criteria. Therefore, the differences do not raise different questions of safety and effectiveness.

- 3D Viewer

In addition to the slice display by MPR, 3D Viewer can display volume data of CT, MR, etc. three-dimensionally by volume rendering.

In the 3D Viewer Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, Heart extraction (non contrast CT), brain anterior region(MRI MRA) and brain posterior

region (MRI MRA) can be extracted manually and abdominal artery (CT), cerebral artery (CT) and cerebral vein (CT) can be extracted automatically. The differences between the new application and Predicate Device are that the automatic extraction of Heart extraction (non contrast CT), brain anterior region(MRI MRA) and brain posterior region (MRI MRA) and performance improvement of abdominal artery (CT), cerebral artery (CT), and cerebral vein (CT). The automatic extraction performance meets the acceptance criteria. Therefore, the differences do not raise different questions of safety and effectiveness.

- General CPR (CT, MR)

General CPR displays CPR images created along a specified centerline.

In the General CPR Application of Synapse 3D Base Tools (V7.0) **(**K243762**)**, Descending Aorta Lumen (CT), Descending Aortic Wall (CT), Arbitrary Inner vessel (CT), and Arbitrary Outer vessel (CT) can be extracted manually. The differences between the new application and Predicate Device are that the automatic extraction of Descending Aorta Lumen (CT), Descending Aortic Wall (CT), Arbitrary Inner vessel (CT), and Arbitrary Outer vessel (CT). The automatic extraction performance meets the acceptance criteria. Therefore, the differences do not raise different questions of safety and effectiveness.

The device features and technical characteristics comparison with predicates is shown as **Table 2** Device Features and Technical Characteristics Comparison Matrix.

Table 2 Device Features and Technical Characteristics Comparison Matrix

Device Parameters	**Synapse 3D Base Tools (V7.2) (This submission)**	**Synapse 3D Base Tools (V7.0) (K243762) (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	QIH, LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same
Decision Date	K254189	05/21/2025	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

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
Reporting	Yes	Yes	Same
Cine	Yes	Yes	Same
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

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
Surface rendering	Yes	Yes	Same
Image subtraction (3D)	Yes	Yes	Same
Time-density distribution	Yes	Yes	Same
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

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
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
Brain Subregion Analysis	Yes	No	Added new feature. Note: The new feature Brain Subregion Analysis is similar to Contour NeuroQuant ("Reference Device"), which was cleared by CDRH via K170981on 09/07/2017. Brain subregion segmentation accuracy in Brain Subregion Analysis compared to expert manual segmentations was evaluated using Dice's coefficient metric and the Dice's coefficients were obtained in the range of 80-90%, the mean percentage

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
			absolute volume differences were in the range1-5%. This added new feature does not raise different questions of safety and effectiveness.
CSF Space Analysis	Yes	No	Added new feature. Note: The new feature CSF Space Analysis is similar to Contour NeuroQuant ("Reference Device"), which was cleared by CDRH via K170981on 09/07/2017. The segmentation accuracy of brain regions in CSF Space Analysis such as the high-convexity SAS (SAS(Upper)), Sylvian fissure and basal cistern (SAS(Lower)), and brain ventricle compared to expert manual segmentations was evaluated using Dice's coefficient metric and the Dice's coefficients were obtained in the range of 80-90%, the mean percentage absolute

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
			volume differences were in the range1-5%. This added new feature does not raise different questions of safety and effectiveness.
Cardiac Function MR	Yes	No	Added new feature. Note: The new feature Cardiac Function MR is similar to Synapse 3D Cardiac Tools ("Reference Device"), which was cleared by CDRH via K200973 on 08/27/2020. This added new feature does not raise different questions of safety and effectiveness.
Calcium Scoring	Yes	No	Added new feature. Note: The new feature Calcium Scoring is similar to Synapse 3D Cardiac Tools ("Reference Device"), which was cleared by CDRH via K200973 on 08/27/2020. This added new feature does not raise different questions of safety and effectiveness.

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
4D Flow	Yes	No	Added new feature. Note: The new feature 4D Flow is similar to Synapse 3D Blood Flow Analysis ("Reference Device"), which was cleared by CDRH via K191544 on 10/18/2019. This added new feature does not raise different questions of safety and effectiveness.
Lung Analysis/Airway	Yes	No	Added new feature. Note: The new feature Lung Analysis/Airway is similar to Synapse 3D Lung and Abdomen Analysis ("Reference Device"), which was cleared by CDRH via K130542 on 06/14/2013. This added new feature does not raise different questions of safety and effectiveness.
Liver Analysis	Yes	No	Added new feature. Note: The new feature Liver Analysis is similar to Synapse 3D Liver and Kidney Analysis ("Reference Device"),

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
			which was cleared by CDRH via K142521 on 12/01/2014. This added new feature does not raise different questions of safety and effectiveness.
Craniotomy/tensor Analysis	Yes	No	Added new feature. Note: The new feature Craniotomy/tensor Analysis is similar to Synapse 3D Tensor Analysis ("Reference Device"), which was cleared by CDRH via K141514 on 09/03/2014. This added new feature does not raise different questions of safety and effectiveness.
Brain Perfusion CT	Yes	No	Added new feature. Note: The new feature Brain Perfusion CT is the similar to Synapse 3D Perfusion Analysis ("Reference Device"), which was cleared by CDRH via K162287 on 04/06/2017. This added new feature

Device Parameters	Synapse 3D Base Tools (V7.2) (This submission)	Synapse 3D Base Tools (V7.0) (K243762) (Primary predicate device)	Comparison
			does not raise different questions of safety and effectiveness.
Flow Analysis	Yes	No	Added new feature. Note: The new feature Flow Analysis is similar to Synapse 3D Blood Flow Analysis ("Reference Device"), which was cleared by CDRH via K191544 on 10/18/2019. This added new feature does not raise different questions of safety and effectiveness.
Post-reconstruction request	Yes	Yes	Same
Spatial reproduction display	Yes	Yes	Same

5. Safety Information

Synapse 3D Base Tools (V7.2) 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.

6. Testing and Performance Information

Nonclinical testing result:

The purpose of Software Development Process for Synapse 3D Base Tools (V7.2) 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 (V7.2) 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 (V7.2) 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 (V7.2) 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

device.

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.

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

The name of extraction algorithm	DICE
Abdominal artery (CT)	0.73
Left brain center point (CT)	0.95
Right bnrain center point (CT)	0.95
Brain (CT)	0.98
Cerebral vessel_Artery (CT)	0.87
Cerebral vessel_Vein (CT)	0.85
Descending Aorta Lumen (Fast mode) (CT)	0.90
Descending Aortic Wall (Fast mode) (CT)	0.94
Descending Aorta Lumen (Normal mode) (CT)	0.90
Descending Aortic Wall (Normal mode) (CT)	0.90
Heart (CT)	0.97
Two point vessel_Inner contour (CT)*	0.88
Two point vessel_Outer contour (CT)*	0.87
Brain subregion MRA Anterior (MRI)_	0.96
Brain subregion MRA Posterior (MRI)	0.96
Brainstem (MRI)	0.97
CSF (MRI)	0.89
Fourth ventricle (MRI)	0.89
Frontal lobe (Left) (MRI)	0.90
Frontal lobe Light (MRI)	0.89
Hippocampus (Left) (MRI)	0.92
Hippocampus (Right) (MRI)	0.93
Lateral ventricle (Left) (MRI)	0.95
Lateral ventricle (Right) (MRI)	0.94
Parietal lobe (Left) (MRI)	0.86
Third ventricle (MRI)	0.91
White matter (Left) (MRI)	0.94
White matter (Right) (MRI)	0.94
Basal ganglia (Left) (MRI)	0.95
Basal ganglia (Right) (MRI)	0.94
Cerebellum (Left) (MRI)	0.97
Cerebellum (Right) (MRI)	0.97
Insular cortex (Left) (MRI)	0.91

Insular cortex (Right) (MRI)	0.91
Limbic system (Left) (MRI)	0.90
Limbic system (Right) (MRI)	0.84
Occipital lobe (Left) (MRI)	0.81
Occipital lobe (Right) (MRI)	0.81
Temporal lobe (Left) (MRI)	0.90
Temporal lobe (Right) (MRI)	0.90
Cardiac left lumen (MRI)	0.90
Cardiac left myocardium (MRI)	0.92
Cardiac right ventricle (MRI)	0.88
Cardiac left ventricle Myocardium (MRI long axis)	0.94
Delay enhance LV (MRI)	0.93
Delay enhance cardiac left lumen (MRI)	0.95
Brain ventricle (MRI)	0.95
Cerebral spinal fluid (MRI)	0.98
SAS (Lower) (MRI)	0.99
SAS (Upper) (MRI)	0.99
Periprostatic tissue (MRI)	0.76
Vagina and cervix (MRI)	0.90

*Here, this extraction is performed semi-automatically. All other extraction functions are executed automatically.

Cybersecurity:

The confidentiality, integrity and availability are maintained by Synapse 3D Base Tools (V7.2) 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 (V7.2) 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 (V7.2) 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.*

- *ISO 20417 First edition 2021-04 Corrected version 2021-12, Medical devices - Information to be supplied by the manufacturer.*
- *IEC 81001-5-1 Edition 1.0 2021-12, Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle.*
- *IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices.*
- *IEC 82304-1 Edition 1.0 2016-10, Health software - Part 1: General requirements for product safety.*

7. Conclusion

Performance tests were conducted to test the functionality of the subject device, Synapse 3D Base Tools (V7.2). Results of all conducted testing demonstrate that the subject device is substantially equivalent to the predicate.