FUJIFILM Corporation
% Jeffrey Wan
Manager, Regulatory Affairs
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

Re: K221677 November 10, 2022
Trade/Device Name: Synapse 3D Base Tools v6.6
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 21, 2022
Received: October 21, 2022

Dear Jeffrey Wan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221677

Device Name
SYNAPSE 3D Base Tools v6.6

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 and dual energy image viewing.
-Imaging tools for MR images including delayed enhancement image viewing, diffusion-weighted MRI image viewing.

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:	November 7, 2022
Submitter's Information:	FUJIFILM Corporation 26-30 NISHIAZABU, 2-CHOME MINATO-KU, TOKYO 106-8620
Contact Person:	Jeffrey Wan Manager, Regulatory Affairs Telephone: (201) 675-8947 Email: jeffrey.wan@fujifilm.com
Device Trade Name:	Synapse 3D Base Tools
Device Common Names:	Medical image management and processing system
Device Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Class:	Class II
Panel:	Radiology
Predicate Devices:	Synapse 3D Base Tools (K203103) FUJIFILM Corporation
Reference Devices	syngo.CT Dual Energy (K133648) Siemens Medical Solutions USA, Inc. PixelShine (K161625) AlgoMedica

1. Description of the Device

Synapse 3D Base Tools (V6.6) (this submission) is updated software of previously-cleared Synapse 3D Base Tools (V6.1) (cleared by CDRH via K203103 on February 9, 2021.

The 3D image analysis software Synapse 3D Base Tools (V6.6) 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 (V6.6), 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 (V6.6) 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 (V6.6) 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.

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 (K203103). 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 (V6.6) (This submission)	Synapse 3D Base Tools(V6.1) (K203103) (Primary predicate device)	Comparison
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulatory Number	892.2050	892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same
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
Volume Rendering and 3D Viewing	Yes	Yes	Same
MPR ▪ orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), ▪ Sector and rectangular shape MPR image viewing	Yes	Yes	Same

Device Parameters	Synapse 3D Base Tools (V6.6) (This submission)	Synapse 3D Base Tools(V6.1) (K203103) (Primary predicate device)	Comparison
▪ MPR for dental images ▪ Multiple MPR images along an object (Slicer)			
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
General image data management and administration tools	Yes	Yes	Same
Segmentation	Yes	Yes	Same
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	Yes	No	Added application of dual

Device Parameters	Synapse 3D Base Tools (V6.6) (This submission)	Synapse 3D Base Tools(V6.1) (K203103) (Primary predicate device)	Comparison
viewing			energy image viewing. Note: The dual energy image viewing feature is the same as the feature available on the syngo.CT Dual Energy ("Reference Device"), which was cleared by the FDA under K133648. Therefore, this added feature does not raise different questions of safety and effectiveness.
PixelShine	Yes	No	This feature is the embedded functionality of previously-cleared PixelShine (cleared by CDRH via K161625).
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 November 4, 2021 issue of the "DRAFT 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. The Dual Energy Analysis module was evaluated via comparative testing on patient data with the reference device syngo.CT Dual Energy (K133648).

Cybersecurity:

The confidentiality, integrity and availability are maintained by Synapse 3D Base Tools in accordance with **Section 6** of the *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Guidance for Industry and Food and Drug Administration Staff (October 2, 2014)*.

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.