September 25, 2018

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD, CT 06902

Re: K181773
Trade/Device Name: Synapse 3D Optional Tools
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 6, 2018
Received: September 7, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181773

Device Name
Synapse 3D Optional Tools

Indications for Use *(Describe)*

Synapse 3D Optional Tools is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals, with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Optional Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including CT, MR. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. Addition to the tools in Synapse 3D Base Tools, Synapse 3D Optional Tools provides:

• Imaging tools for CT images including virtual endoscopic viewing.
• Imaging tools for MR images including delayed enhancement image viewing and diffusion-weighted MRI data analysis.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FUJIFILM Medical Systems U.S.A., Inc.,
Synapse 3D Optional Tools (V5.2) 510(k)

510(k) Summary

Date Prepared: July 1, 2018

Submitter's Information: FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902
Telephone: (301) 251-1092
Fax: (203) 602-3785
Contact: Jeffrey Wan

Device Trade Name: Synapse 3D Optional Tools

Device Common Names: Picture Archiving and Communications System (PACS)

Device Clasification Name: System, Image Processing, Radiological

Product Code: LLZ

Regulation Number: 21 CFR 892.2050

Device Class: Class II

Panel: Radiology

Primary Predicate Devices: Synapse 3D Base Tools (K120361), FUJIFILM Medical Systems U.S.A., Inc.

Reference Predicate Devices: REX™ (K021099), PointDx, Inc.
Olea Sphere V3.0 (K152602), Olea Medical

1. Description of the Device

Synapse 3D Optional Tools is an optional software module that works with Synapse 3D Base Tools (cleared by via K120361 on 04/06/2012). 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 retrieves image data via network communication based on the DICOM standard. The retrieved image data are stored on the local disk managed by Synapse 3D Base Tools, and the associated image-related information of the image data is registered in the database and used for display, image processing, analysis, etc.

Synapse 3D Optional Tools provides imaging tools for CT and MR images such as virtual endoscopic simulator (CT) (referred collectively as “Endoscopic Simulator”), diffusion-weighted MRI data analysis (MR) (referred collectively as “IVIM”), and delayed enhancement image viewing (MR) (referred collectively as “Delayed Enhancement”). The software can display the images on a display monitor, or printed them on a hardcopy using a DICOM printer or a Windows printer.

Synapse 3D Optional Tools runs on Windows standalone and server/client configuration installed on a commercial general-purpose Windows-compatible computer. It offers software tools which can be used by trained professionals, such as radiologists, clinicians or general practitioners to interpret medical images obtained from various medical devices to create reports or develop treatment plans.

2. Indications for Use

Synapse 3D Optional Tools is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals, with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Optional Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including CT, MR. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. Addition to the tools in Synapse 3D Base Tools, Synapse 3D Optional Tools provides:

・Imaging tools for CT images including virtual endoscopic viewing.

・Imaging tools for MR images including delayed enhancement image viewing and diffusion-weighted MRI data analysis.

3. Substantial Equivalence Comparison

Synapse 3D Optional Tools has the same intended use, similar labeling, and clinical application tools as those of the cleared primary predicate device Synapse 3D Base Tools (K120361).and reference predicate devices REX, VERSION 1.0 (K021099) and Olea Sphere V3.0 (K152602). The device features and technical characteristics comparison with predicate and reference devices is shown as Table 1.

Table 1 Device Features and Technical Characteristics Comparison Matrix

Device Parameters	**Synapse 3D Optional Tools (This submission)**	**Synapse 3D Base Tools (K120361) (Primary predicate device)**	**REX™** (K021099) (Reference device)	**Olea Sphere V3.0** (K152602) (Reference device)
2D Viewing	Yes	Yes	Yes	Yes
Image Storing (DICOM SCP)	Yes	Yes	N/A	Yes
Image Communication (DICOM SCU)	Yes	Yes	Yes	Yes
DICOM Interface (SCP/SCU)	Yes	Yes	Yes	Yes
Printing (DICOM SCU)	Yes	Yes	N/A	N/A
Measurements (2D and 3D)	Yes	Yes	Yes	Yes
Annotations - Standardized and Free Text	Yes	Yes	Yes	Yes
Reporting	Yes	Yes	Yes	Yes
Cine	Yes	Yes	N/A	N/A
Volume Rendering and 3D Viewing	Yes	Yes	Yes	Yes
MPR ▪ orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), ▪ Sector and rectangular shape MPR image viewing ▪ Multiple MPR images	Yes	Yes	Yes	Yes

along an object (Slicer)				
Maximum, Average, Minimum Intensity Projection	Yes	Yes	N/A	N/A
4D viewing	Yes	Yes	N/A	N/A
Image fusion	Yes	Yes	N/A	N/A
Surface rendering	Yes	Yes	N/A	N/A
Image subtraction (3D)	Yes	Yes	N/A	N/A
Time-density distribution	Yes	Yes	N/A	N/A
General image data management and administration tools	Yes	Yes	Yes	Yes
Real time display of endoscopic view	Yes	N/A	Yes	N/A
Internal and external viewing of any hollow structure	Yes	N/A	Yes	N/A
Visualizing the diffusion properties (IVIM map) from the analysis of diffusion-weighted MRI data	Yes	N/A	N/A	Yes
Display of delayed enhancement MR images	Yes	N/A	N/A	N/A
Hardware Platform	Windows PC	Windows PC	Windows PC	Windows PC

4. Safety Information

Synapse 3D Optional Tools introduces no new safety or efficacy issues other than those already indentified with the predicate devices. The Risk Management and the results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "*Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*." The Synapse 3D Optional 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 Optional 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 Optional Tools did not require clinical studies to support safety and effectiveness of the software.

Verification and Validation:

The purpose of Software Development Process for Synapse 3D Optional Tools is to carry out the activities relating to the establishment of the software development plan (or plans) for definitely conducting software requirement analysis, architectural design, the detailed design, unit implementation and verification, software integration and integration testing, software system test, software release, software maintenance. Testing 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 Optional 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 Optional 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.

Cybersecurity:

The confidentiality, integrity and availability are maintained by Synapse 3D Optional 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 Optional 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 communication based on the DICOM standard. Therefore Synapse 3D Optional Tools assure an adequate degree of protection for cybersecurity.

Performance standards:

- *Digital Imaging and Communications in Medicine (DICOM) Set (PS 3.1 – 3.20) (2016).*
- *AAMI / ANSI / IEC 62304:2006, Medical Device Software - Software Life CycleProcesses.*
- *ISO 14971 Second Edition 2007-03-01, 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 Optional Tools. Results of all conducted testing were acceptable in supporting the claim of substantial equivalence.