FUJIFILM Corporation
% Mr. Jeffrey Naveda
Site Director, Regulatory and Quality Affairs
FUJIFILM Medical Systems U.S.A., Inc.
3020 Carrington Mill Blvd.
MORRISVILLE NC 27560

April 25, 2019

Re: K183248
Trade/Device Name: Synapse Enterprise Viewer Version 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 15, 2019
Received: April 16, 2019

Dear Mr. Naveda:

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,

Michael D. O'Hara For

Thalia T. Mills, 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)*
K183248

Device Name
Synapse Enterprise Viewer Version 1.0

Indications for Use *(Describe)*
Synapse Enterprise Viewer (EV) is a software-based enterprise image viewer used with general purpose servers and dedicated reading workstations. It allows for communication, reformatting, rendering on the server component and communication and display of DICOM and non-DICOM images as well as reports.

The device is intended for use as a diagnostic, review and analysis tool by trained professionals such as radiologists, physicians and technologist. Synapse EV is not intended for diagnostic use on mobile devices.

Synapse Enterprise Viewer is not to be used for primary mammography diagnosis.

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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5) 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

5a) Submitter

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TOKYO 106-8620
JAPAN
FDA Establishment Registration Number: 3005930550

Contact Person
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Date Prepared: November 14, 2018

5b) Device

Trade Name:	Synapse Enterprise Viewer Version 1.0
Common Name:	Medical Information and Image Management Software
Regulatory Class:	II
Classification Panel:	Radiology
Regulation Name:	Picture archiving and communications system
Regulation Number:	892.2050
Product Code:	LLZ

5c) Predicate Device

K161130 – **Calgary Scientific Inc. ResolutionMD®**

No reference devices were used in this submission.

5d) Device Description

The Synapse Enterprise Viewer Software Version 1.0 (Hereafter referred to as Synapse EV), the subject of this Premarket Notification Submission, is intended for communication, storage, display, manipulation, measurement, printing, and processing of radiological data including images, reports, patient status and clinical information acquired from various medical imaging and information systems. This software device provides post processing of existing medical images; it does not control how the medical images are acquired.

Synapse EV is a multipurpose, enterprise wide application used for Radiologist interpretation, in-house clinical review, and physician image and information access. It is a web-based, zero-download viewer that uses Internet technology at the foundation of its design. This design allows for a user interface that takes advantage of familiar functions of modern browsers and can be used as a web application on a PC or Mobile device.

As a zero-download viewer application, Synapse is accessible by anyone connected to a Synapse web server via an intranet or the Internet over standard HTTP or a secure HTTPS (SSL) connection. Synapse users may be assigned different security levels to access patient and study folders. All tools are available to all users regardless of their physical location or health provider function.

Compatible with both Intranet and Internet network connections, an installed Synapse EV Software will typically be comprised of one or more Synapse EV Servers. As the client a standard browser is being used.

5e) Indications for use

Synapse Enterprise Viewer (EV) is a software-based enterprise image viewer used with general purpose servers and dedicated reading workstations. It allows for communication, reformatting, rendering on the server component and communication and display of DICOM and non-DICOM images as well as reports.

The device is intended for use as a diagnostic, review and analysis tool by trained professionals such as radiologists, physicians and technologists. Synapse EV is not intended for diagnostic use on mobile devices.

Synapse Enterprise Viewer is not to be used for primary mammography diagnosis.

5f) Comparison of Technological Characteristics

Both Synapse Enterprise Viewer v1.0 and the predicate device, ResolutionMD® are enterprise viewers used with standard browsers for visualization of radiological images on web and mobile devices. Both are software-only devices for post processing of existing images and do not control how the medical images are acquired. Both Synapse Enterprise Viewer v1.0 and ResolutionMD® provide display, reformatting, and communication of DICOM and common non-DICOM file types.

Platforms for both Synapse Enterprise Viewer v1.0 and the predicate device, ResolutionMD® are general servers, web browsers on PC and specific mobile devices. Features which are the same for Synapse Enterprise Viewer v1.0 and the predicate device are that both run within a standard browser and do not require user installation, have data encryption and security in transit, use standard TCP/IP network protocol and support commonly used modalities. Both have the same search and results display features as well as viewer features such as image loading, viewing, measurement and the availability of the User Guide. Image scrolling, layouts, freehand annotation and measurement features are the same for Synapse Enterprise Viewer v1.0 and the predicate device.

The primary differences in features are that the predicate device offers collaboration and conferencing functionalities and allows multitenancy, while the current device does not. The predicate device offers more 2D viewer functionality as well as 3D viewer features, maximum intensity projection and multi-planar reformatting which the current device does not. There are additional minor differences in features with regard to involve reporting, image manipulation and printing functionality as well as differences in a few supported modalities, supported video formats, and search and results display features.

The subject of this 510(k) submission, Synapse Enterprise Viewer v1.0, did not require clinical studies to support safety and effectiveness of the software. Software development and testing for both the current and predicate devices is in compliance with the IEC 62304 “Medical device software – Software life cycle processes” standard. Software verification on the system level includes integration testing for all components. Selected simulated workflow validation and new feature validation was performed by product owners who have

comprehensive understanding of user requirements as well as clinical expertise to validate the design and behavior of the implemented features and functionality. User Guide validation was performed by the test engineering team. Any defects logged as unresolved anomalies do not impact device safety or effectiveness.

5g) Conclusions

The Synapse Enterprise Viewer v1.0 has the same general intended use, and similar indications for use, principles of operation, and technological characteristics as the predicate device ResolutionMD.® (K161130). Both are intended for use as a diagnostic, review and analysis tool by trained professionals such as radiologists, physicians and technologists and are software-only devices for post processing of existing images. The implemented design controls, risk management activities, labeling, and verification and validation testing demonstrate the safety and efficacy of the current device. Software development and testing for both the current and predicate devices complies with the IEC 62304 “Medical device software – Software life cycle processes” standard. Differences in features or functionality do not raise issues of safety or effectiveness. Thus, Synapse Enterprise Viewer Version 1.0 is substantially equivalent to the predicate device.