FUJIFILM Corporation
% Mr. Tommy San
Regulatory Affairs Specialist
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

August 27, 2020

Re: K200973
Trade/Device Name: Synapse 3D Cardiac Tools
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 27, 2020
Received: July 28, 2020

Dear Mr. San:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200973

Device Name
Synapse 3D Cardiac Tools

Indications for Use *(Describe)*

Synapse 3D Cardiac 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 Cardiac Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA.

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 Cardiac Tools provides the tools for specific clinical applications which provide targeted workflows, custom UI, targeted measurements and reporting functions including:

Functional cardiac analysis for CT left ventriculography images: which is intended to evaluate the functional characteristics of heart.

-Functional cardiac analysis for MR heart images: which is intended to evaluate the functional characteristics of heart.

-Coronary artery analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries.

-Coronary artery analysis for MR heart images: which is intended for the qualitative and quantitative analysis of coronary arteries.

-Calcium scoring for non-contrast CT heart images: which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.

-Cardiac Fusion: which is intended to analyze cardiac anatomy and pathology with a fused image of functional data (e.g. NM image, Bulls eye) and anatomical data.

-Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves, measurement of the calcification area in the aorta and the valves. Placement of a virtual prosthetic valve.

-MR parametric maps: which is provided for pixel maps for myocardial MR relaxation times.

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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510(k) Summary

K200973

Date Prepared:	April 10, 2020
Submitter's Information:	FUJIFILM Corporaton 26-30,NISHIAZABU 2-CHOME MINATO-KU TOKYO 106-8620 Telephone: (781) 323-5315 Contact: Tommy San
Device Trade Name:	Synapse 3D Cardiac 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
Predicate Devices:	Synapse 3D Cardiac Tools (K130383) FUJIFILM Medical Systems U.S.A., Inc.

1. Description of the Device

Synapse 3D Cardiac Tools (V5.4) is an optional software module that works with Synapse 3D Base Tools (V3.0) (cleared by CDRH via K120361 on 04/06/2012) that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Cardiac Tools (V5.4) accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA. The main functions of Synapse 3D Cardiac Tools are shown below.

- Cardiac Function (CT)
- Cardiac Function (MR)
- Coronary Artery Analysis (CT)
- Calcium Scoring
- Cardiac Fusion
- Coronary Artery Analysis (MR)
- Aortic Valve Analysis
- MR Flow Analysis (MR)
- 4-Chamber Analysis (CT)
- Cardiac Ablation Analysis (CT)
- Cardiac Tx-maps
- Mitral Valve Analysis

Synapse 3D Cardiac 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 Cardiac 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 Cardiac Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA.

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 Cardiac Tools provides the tools for specific clinical applications which provide targeted workflows, custom UI, targeted measurements and reporting functions including:

- Functional cardiac analysis for CT left ventriculography images: which is intended to evaluate the functional characteristics of heart.
- Functional cardiac analysis for MR heart images: which is intended to evaluate the functional characteristics of heart.
- Coronary artery analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries.
- Coronary artery analysis for MR heart images: which is intended for the qualitative and quantitative analysis of coronary arteries.
- Calcium scoring for non-contrast CT heart images: which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.
- Cardiac Fusion: which is intended to analyze cardiac anatomy and pathology with a fused image of functional data (e.g. NM image, Bulls eye) and anatomical data.
- Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves, measurement of the calcification area in the aorta and the valves. Placement of a virtual prosthetic valve.
- MR parametric maps: which is provided for pixel maps for myocardial MR relaxation times.

3. Substantial Equivalence Comparison

Synapse 3D Cardiac Tools has the same intended use, similar labeling, and clinical application tools as those of the cleared predicate device Synapse 3D Cardiac Tools (K130383). 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 Cardiac Tools(V5.4) (This submission)**	**Synapse 3D Cardiac Tools(V3.2) (K130383) Primary predicate**
Segmentation of heart	Yes	Yes
3D viewing of heart	Yes	Yes
Functional cardiac analysis (CT, MR)		
• Identifying left ventricle	Yes	Yes
• Cardiac functional parameter measurement	Yes	Yes
• Bulls eye display	Yes	Yes
Coronary artery analysis (CT, MR)		
• Coronary artery extraction	Yes	Yes
• Stenosis and plaque measurement	Yes	Yes
• CPR view of coronary arteries	Yes	Yes
Calcium scoring	Yes	Yes
Cardiac fusion	Yes	Yes
Valve Analysis	Yes	N/A
MR parametric maps (such as T1 relaxation)	Yes	N/A
Reporting of results	Yes	Yes
Product Availability	Software Product	Software Product
Hardware Platform	Windows PC	Windows PC
Operating System	For Server: Microsoft® Windows Server®2016 Standard Edition Microsoft® Windows Server® 2012 R2 Update 1 Standard Edition For Client:	For Server: Windows Server 2008 For Client: Windows XP Pro SP2up Windows Vista BE SP1up Windows 7 Pro SP1

Device Parameters	Synapse 3D Cardiac Tools(V5.4) (This submission)	Synapse 3D Cardiac Tools(V3.2) (K130383) Primary predicate
	Microsoft Windows 10 (x64, x86) Microsoft Windows 8.1 (x86, x64) Microsoft Windows 7 Professional (x86, x64) SP1	

4. Safety Information

Synapse 3D Cardiac 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 Cardiac 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 Cardiac 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 Cardiac 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 Cardiac 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 Cardiac 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 Cardiac 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 Cardiac 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 Cardiac 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).*
- *AAMI / ANSI / IEC 62304:2006, Medical Device Software - Software Life Cycle Processes.*
- *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 Cardiac Tools. Results of all conducted testing were acceptable in supporting the claim of substantial equivalence.