DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 6, 2017

FUJIFILM Medical Systems U.S.A., Inc.
% Jyh-Shyan Lin, Ph.D.
Senior Manager, Regulatory, Quality and Clinical Affairs
419 West Avenue
STAMFORD CT 06902

Re: K162287
Trade/Device Name: Synapse 3D Perfusion Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, JAK
Dated: March 13, 2017
Received: March 15, 2017

Dear Dr. Lin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162287

Device Name
Synapse 3D Perfusion Analysis

Indications for Use *(Describe)*

Synapse 3D Perfusion Analysis 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 Perfusion Analysis accepts DICOM compliant medical images acquired from CT and MR. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Base Tools, Synapse 3D Perfusion Analysis provides the parameter images by post-processing of dynamic scanned CT arteriography and magnetic resonance (MR) images acquired with contrast agents to aid the assessment of cerebral (CT and MR), myocardial (CT) and abdomen (CT) blood flows. The parameter images are 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.

510(k) Summary

Date Prepared:

March 11, 2017

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: Jyh-Shyan Lin

Device Trade Name:

Synapse 3D Perfusion Analysis

Device Common Names:

Picture Archiving and Communications System (PACS)

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 Brain Perfusion (K120637), FUJIFILM Medical Systems U.S.A., Inc.
- syngo CT Myocardial Perfusion (K150713), Siemens Medical Solutions USA, Inc.
- syngo Volume Perfusion-CT Body (K092013), Siemens Medical Solutions USA, Inc.

1. Description of the Device

Synapse 3D Perfusion Analysis is medical device software for Perfusion Analysis that provides the parameter images by post-processing of dynamic scanned CT arteriography and MR images acquired with contrast agents to aid the assessment of cerebral (CT and MR), myocardial (CT) and abdomen (CT) blood flows. The parameter images are Blood Volume (BV), Blood Flow (BF), Mean Transit Time (MTT), and Time to Peak (TTP). The perfusion parameter images can be presented to the trained medical professionals as the time-density curves (TDC) and perfusion characteristics maps (in parametric and summary) to assist them in assessing the blood flows. Synapse 3D Perfusion Analysis includes the following perfusion analysis applications.

(1) Brain Perfusion (CT and MR) (unchanged from the FDA-cleared version K120637) is an application that analyzes the cerebral blood flow using the contrast-enhanced dynamic scanned CT and MR cerebral arteriography images. The Brain Perfusion post-processes the cerebral arteriography CT and MR images, and generates the parameter images of Cerebral Blood Volume (CBV), Cerebral Blood Flow (CBF), MTT, and TTP.

(2) 4D Perfusion (CT) is an application that analyzes the changes in the cerebral blood flow over time (in 4D) using the contrast-enhanced multi-phase 3D whole-brain images. The 4D Perfusion post-processes the cerebral arteriography CT and MR images, and generates the 4D (over time) parameter images of CBV, CBF, MTT, and TTP.

(3) Abdominal Perfusion (CT) is an application that analyzes the blood flow of abdominal organs over time (in 4D) using the contrast-enhanced multi-phase 3D abdomen images. The Abdominal Perfusion post-processes the abdominal CT images, and generates the parameter images of Tissue Blood Volume (TBV), Tissue Blood Flow (TBF), MTT, and TTP.

(4) Cardiac Perfusion (CT) is an application that analyzes the myocardial blood flow using the multi-phase 3D heart images. The Cardiac Perfusion post-processes the contrast-enhanced Myocardial CT images, and generates the parameter images of Myocardial Blood Volume (MBV), Myocardial Blood Flow (MBF), MTT, and TTP.

Synapse 3D Perfusion Analysis runs on Windows standalone and server/client configuration installed on a commercial general-purpose Windows-compatible computer. Synapse 3D Perfusion Analysis is an optional software module that works with Synapse 3D Base Tools (cleared by CDRH via K120361 on 04/06/2012) which 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. 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 is used for display, image processing, analysis, etc. Synapse 3D Perfusion Analysis can handle images of CT and MR. The software can display the images on a display monitor, or printed them on a hardcopy using a DICOM printer or a Windows printer.

2. Indications for Use

Synapse 3D Perfusion Analysis 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 Perfusion Analysis accepts DICOM compliant medical images acquired from CT and MR. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Base Tools, Synapse 3D Perfusion Analysis provides the parameter images by post-processing of dynamic scanned CT arteriography and magnetic resonance (MR) images acquired with contrast agents to aid the assessment of cerebral (CT and MR), myocardial (CT) and abdomen (CT) blood flows. The parameter images are Blood Volume (BV), Blood Flow (BF), Mean Transit Time (MTT), and Time To Peak (TTP).

3. Substantial Equivalence Comparison

Synapse 3D Perfusion Analysis has the same intended use, similar labeling, and clinical application tools as those of the cleared predicate devices. It assesses the blood flows in the same intended body parts of the predicate devices (Table 1).

Table 1. Perfusion analysis in different body parts

Subject body parts	Predicate devices	510(k) #
Cerebral region	Synapse 3D Brain Perfusion	K120637
Cardiac region	syngo.CT Myocardial Perfusion	K150713
Abdomen region	syngo Volume Perfusion-CT Body	K092013

Synapse 3D Perfusion Analysis provides the parameter images by post-processing of dynamic scanned CT arteriography and magnetic resonance (MR) images acquired with contrast agents to aid the assessment of cerebral (CT and MR), myocardial (CT) and abdomen (CT) blood flows. The parameter images are Blood Volume (BV), Blood Flow (BF), Mean Transit Time (MTT), and Time To Peak (TTP) (Table 2).

Table 2. Device features and technological characteristics comparison

Device Parameters	Synapse 3D Perfusion Analysis (This submission)	Synapse 3D Brain Perfusion (K120637)	Syngo.CT Myocardial Perfusion (K150713)	syngo Volume Perfusion-CT Body (K092013)
DICOM compliant CT images with contrast image handling	Yes*	Yes	Yes	Yes
DICOM compliant MR images with contrast agent handling	Yes	Yes	No	No

Time-Signal Curve	Yes	Yes	Yes	Yes
Time to Peak image	Yes	Yes	Yes	Unknown
Parameter images: • Blood Volume • Blood Flow • Mean Transit Time	Yes	Yes	Yes	Yes

*Yes: Equivalent features and technological characteristics

4. Safety Information

Synapse 3D Perfusion Analysis introduces no new safety or efficacy issues other than those already indentified with the predicate device. 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 Perfusion Analysis 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

Synapse 3D Perfusion Analysis is tested successfully with reference to its product requirements, as well as design verification and validation documents and traceability matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse 3D Perfusion Analysis software, which is found to be safe and effective and substantially equivalent to the predicate devices.

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, we conducted benchmark performance testing using actual clinical images to help demonstrate that the proposed device 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 successfully passed.

The data used for performance testing are defined as follows.

- Input data (Pi): an image which is created using an arbitrary CT signal value.
- Reference data (Pt): a value derived from perfusion calculation model using the input data (Pi).
- Result data (Pc): a value calculated by Synapse 3D Perfusion Analysis using the input data (Pi).
- Error: ((Pt - Pc) / Pt)*(100%).
- Pass criteria: the error is within ± 1%.

Based on the above definitions for the performance testing data, all of the test cases were tested and the performance testing results (accuracy test results including uncertainties) were passed.

6. Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate device.