DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

December 1, 2014

Re: K142521
Trade/Device Name: Synapse 3D Liver and Kidney Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 10, 2014
Received: November 12, 2014

Dear Mr. 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

Janine M. Morris
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)*
K142521

Device Name
SYNAPSE 3D Liver and Kidney Analysis

Indications for Use *(Describe)*

Synapse 3D Liver and Kidney Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Liver and Kidney Analysis accepts DICOM compliant medical images. 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 Liver and Kidney Analysis uses contrast enhanced images of the body and provides custom workflows and UI, and reporting functions for liver and kidney analysis including, liver and peripheral organ segmentation, and tumor segmentation. Also segmentation of intrahepatic and peripheral vessels as well as the approximation of vascular territories is provided using contrast enhanced computed tomographic images.

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.

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510(k) Summary

Date Prepared:

September 5, 2014

Submitter's Information:

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419 West Avenue
Stamford, Connecticut 06902
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Fax: (203) 602-3785
Contact: Jyh-Shyan Lin

Device Trade Name:

Synapse 3D Liver and Kidney Analysis

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Description of the Device

Synapse 3D Liver and Kidney Analysis (V4.0) (this submission) is updated software of previously-cleared Synapse 3D Liver Analysis (cleared by CDRH via K110186 on 04/07, 2011) with expanded IFU and revised device name. The new feature in Synapse 3D Liver and Kidney Analysis (V4.0) are Kidney Analysis (CT) function and Liver Analysis (MR).

Synapse 3D Liver and Kidney Analysis is medical application software running 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 to develop treatment plans.

Synapse 3D Liver and Kidney 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 medial 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 Liver and Kidney 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.

The liver and kidney analysis tools both segment the organs, peripheral organs and vessels using similar body part recognition algorithms already available in the FDA-cleared Base Tools (K120361) and the Liver Analysis (CT) (K110186). The technical characteristics and principles of operations are described in details in the Device Description section, which includes the Liver Analysis (CT and MR) and Kidney Analysis (CT). Based on the cleared functions, Synapse 3D Liver and Kidney Analysis enhances the custom workflows and UI to improve the usability.

Synapse 3D Liver and Kidney Analysis with 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 Liver and Kidney Analysis also can be integrated with Fujifilm's Synapse Cardiovascular for cardiology purposes.

In summary, this 510(k) submission introduces the Synapse 3D Liver and Kidney Analysis with the added capability of performing Liver (MR) and Kidney (CT) Analysis.

Indication for Use

Synapse 3D Liver and Kidney Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Liver and Kidney Analysis accepts DICOM compliant medical images. 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 Liver and Kidney Analysis uses contrast enhanced images of the body and provides custom workflows and UI, and reporting functions for liver analysis including, liver and peripheral organ segmentation, and tumor segmentation. Also segmentation of intrahepatic vessels as well as the approximation of vascular territories is provided using contrst enhanced computed tomographic images.

Predicate Devices:

- VitreaAdvanced (K121213), Vital Images, Inc.
- IQQA-Liver Multimodality software (K131498), EDDA Technology

Technological Characteristics

The proposed Synapse 3D Liver and Kidney Analysis and the predicate devices, i.e., VitreaAdvanced (K121213) and IQQA-Liver Multimodality software (K131498), are medical application software running on Windows operating system installed on commercial general-purpose Windows-compatible computers. These devices are connected to CT and MR with DICOM standard and retrieve image data via network communications. These devices provide 3D image visualization and manipulation tools for medical images with various user interfaces and measurement tools for analysis of rendered images. The Synapse 3D Liver and Kidney Analysis and the predicate devices support the workflows, UI, and reporting functions for analyzing the images of the liver (MR and CT) and kidney (CT), which are abdomen organs.

Safety Information

Synapse 3D Liver and Kidney Analysis 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 Liver and Kidney Analysis labeling contains instructions for use and necessary cautions, warnings and notes to provide the safe and effective use of the device.

Testing and Performance Information

Synapse 3D Liver and Kidney Analysis is tested successfully with reference to its Software Requirements Specification, 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 Liver and Kidney Analysis software, which is found to be safe and effective and substantially equivalent to the predicate devices.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the bench 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.

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 devices.