



September 3, 2014

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: K141514  
Trade/Device Name: Synapse 3D Tensor Analysis  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: August 20, 2014  
Received: August 22, 2014

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

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K141514

Device Name

Synapse 3D Tensor Analysis

Indications for Use (Describe)

Synapse 3D Tensor Analysis is medical imaging software used with Synapse 3D Base Tools to accept, display, and process DICOM compliant 2D and 3D medical images acquired from MR for the purpose of viewing of local water diffusion properties and directional dependence of the diffusion in the white matter. It is intended to be used by trained medical professionals in reading, interpreting, reporting, screening and treatment planning.

Addition to the general 2D and 3D image processing and measurement tools available in Synapse 3D Base Tools, Synapse 3D Tensor Analysis provides custom workflows, UI, and reporting functions for tensor analysis with neck and head MR images. It includes display of diffusion and FA color map images, white matter tractography, dynamic review in MR, vessel and body visualization with registration of MR, CT, XA, PET and NM.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

## 510(k) Summary

**Date Prepared:**

August 20, 2014

**Submitter's Information:**

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Contact: Jyh-Shyan Lin

**Device Trade Name:**

Synapse 3D Tensor 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 Tensor Analysis is an optional software module that works with Synapse 3D Base Tools, cleared by CDRH via K120361 on 04/06/2012. Synapse 3D Tensor Analysis, Synapse 3D Base Tools and other optional software modules consist of the Synapse 3D product family.

Synapse 3D is medical application software running on a Standalone PC or Windows server/client configuration installed on a commercial general-purpose Windows-compatible computer. It offers provides custom workflows, UI, and reporting functions for trained medical professionals to aid them in reading, interpreting, reporting, screening and treatment planning.

Synapse 3D Tensor Analysis supports the display of diffusion and Fractional anisotropy (FA) colormap images, white matter tractography, dynamic review, vessel and body visualization with registration of MR, CT, XA, PET and NM. Tensor Analysis tool enables tensor analysis from diffusion-weighted MR images and tractography-based extraction and observation of local water diffusion properties and directional dependence of the diffusion in the white matter. Additional images (mainly CT images) can be loaded, and skin, bone, brain parenchyma, tumor, and cerebral vessels can be extracted in craniotomy simulations.

The main functions are shown below.

- Display FA and diffusion colormap images
- Extract and observe white matter
- Calculate FA value, number of fibers, area, and volume in the specified ROI
- Simultaneous display of white matter and skin, bone, brain parenchyma, tumor, artery, vein, and other regions
- Craniotomy simulations involving cutting of skin and bone regions, brain surface clipping by depth, and tumor plane clipping

## **Indication for Use**

Synapse 3D Tensor Analysis is medical imaging software used with Synapse 3D Base Tools to accept, display, and process DICOM compliant 2D and 3D medical images acquired from MR for the purpose of viewing of local water diffusion properties and directional dependence of the diffusion in the white matter. It is intended to be used by trained medical professionals in reading, interpreting, reporting, screening and treatment planning.

Addition to the general 2D and 3D image processing and measurement tools available in Synapse 3D Base Tools, Synapse 3D Tensor Analysis provides custom workflows, UI, and reporting functions for tensor analysis with neck and head MR images. It includes display of diffusion and FA color map images, white matter tractography, dynamic review in MR, vessel and body visualization with registration of MR, CT, XA, PET and NM.

## **Predicate Devices:**

- Visia™ Neuro (K113701), MeVis Medical Solutions AG
- Synapse 3D Base Tools (K120361), FUJIFILM Medical Systems U.S.A., Inc.
- Ready View (K113456), GE Healthcare

### **Technological Characteristics**

The proposed Synapse 3D Tensor Analysis and the predicate devices, i.e., Visia™ Neuro (K113701) and Synapse 3D Base Tools (K120361), 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 Tensor Analysis and the predicate devices support the workflows, UI, and reporting functions for the Tensor Analysis and Craniotomy Simulations.

### **Safety Information**

Synapse 3D Tensor Analysis introduces no new safety or efficacy issues other than those already identified 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 Tensor 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 Tensor 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 Tensor 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. In addition, a comparative performance testing was conducted between the Synapse 3D Tensor Analysis and the predicate device, and the comparison test result supported the substantial equivalence of the devices’ performance characteristics.

### **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.