MAR - 4 2011

K103687

5. 510(k) Summary

Date Prepared:

December 16, 2010

Submitter's Information:

FUJIFILM Medical Systems USA, Inc.
419 West Avenue
Stamford, Connecticut 06902

Telephone: (203) 602-3774
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Contact: Debra A. Peacock

Device Trade Name:

Synapse 3D Cerebral 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 Communication System (PACS)

Panel:

Radiology

Product Code:

90-LLZ

Date Received:

TBD

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Ms. Debbie Peacock
Regulatory Affairs Manager
FUJIFILM Medical Systems, USA Inc.
419 West Avenue
STAMFORD CT 06902

MAR - 4 2011

Re: K103687
Trade/Device Name: Synapse 3D Cerebral Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 17, 2010
Received: December 17, 2010

Dear Ms. Peacock:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103687

Device Name: Synapse 3D Cerebral Analysis

Indications for Use:

Synapse 3D Cerebral Analysis is medical imaging software used with Synapse 3D Basic 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 Cerebral Analysis accepts DICOM compliant medical images acquired from CT.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Basic Tools, Synapse 3D Cerebral Analysis provides the parameter images by post-processing with dynamic scanned CT cerebral arteriography images to aid the assessment of cerebral blood flow. The parameter images are Cerebral Blood Volume (CBV), Cerebral Blood Flow (CBF), Mean Transit Time (MTT), and Time To Peak (TTP).

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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