K101662

5. 510(k) Summary

JUL 2 6 2010

Date Prepared:

May 27, 2010

Submitter's Information:

FUJIFILM Medical Systems USA, Inc.
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Stamford, Connecticut 06902

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Device Trade Name:

Synapse 3D Basic Tools

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

FUJIFILM Medical Systems U.S.A. Inc.,
Synapse 3D Basic Tools 510(k)

Decision Date:

TBD

Decision:

TBD

Predicate Devices:

- Voxar 3D Enterprise with ColonMetrix and PET/CT Perfusion (Voxar)
  510(k) #: K070831, cleared by CDRH on May 22, 2007.
- Aquarius APS Server (iNtuition) (TeraRecon)
  510(k) #: K061214, cleared by CDRH on May 15, 2006

Description of the Device

The Synapse 3D Basic Tools software 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. The SYNAPSE 3D Basic Tools software runs on Windows Vista or Windows Server 2008 installed on commercial general-purpose Windows-compatible computers. SYNAPSE 3D Basic Tools is connected through DICOM standard to other medical devices such as CT, MR, CR, US, NM, PT, XA, etc. and to a PACS system storing data generated by these medial devices. Image data obtained from these devices are used for display, image processing, analysis, etc. SYNAPSE 3D Basic Tools cannot be used to interpret Mammography images.

SYNAPSE 3D Basic Tools can be integrated with Synapse Workstation (cleared by CDRH via K051553 on 07/07/2005) and can be used as a part of a SYNAPSE system.

Intended For Use

The Synapse 3D Basic Tools is medical imaging software 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. The Synapse 3D Basic Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, CR, US, NM, PT, and XA, etc.

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

The Synapse 3D Basic Tools provides several levels of tools to the user:

- Basic imaging tools for general images, such as 2D viewing, volume rendering and 3D volume viewing, orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), Maximum (MIP), Average (RaySum) and Minimum (MinIP) Intensity Projection, 4D volume viewing, image fusion, image subtraction, CT PET fusion, surface rendering, sector and rectangular shape MPR image viewing, time-density distribution, basic image processing, CINE, measurements, annotations, reporting, printing, storing, distribution, and general image management and administration tools, etc.
- Tools for regional segmentation of anatomical structures within the image data, path definition through vascular and other tubular structures, and boundary detection.

Technological Characteristics

Synapse 3D Basic Tools introduces no new safety or efficacy issues other than those already indentified with the predicate devices. 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."

Testing

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the proposed device.

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.

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.

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

Fujifilm Medical Systems, USA, Inc.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

JUL 26 2010

Re: K101662
Trade/Device Name: Synapse 3D Basic Tools
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 30, 2010
Received: July 1, 2010

Dear Mr. Conry:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101662

Indications for Use

510(k) Number (if known):

JUL 2 6 2010

Device Name: _Synapse 3D Basic Tools

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Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

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

510K K101662