K103720

5. 510(k) Summary

MAR 16 2011

Date Prepared:

December 20, 2010

Submitter's Information:

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

Telephone: (203) 602-3665
Fax: (203) 251-7863
Contact: Kimerly A. Sharp

Device Trade Name:

Synapse 3D Lung and Abdomen 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

Decision Date:

TBD

Decision:

TBD

Predicate Devices:

- Lung Nodule Assessment and Comparison Option (K023785), Philips
- Aquarius Workstation (K011142), TeraRecon

Description of the Device

Synapse 3D Lung and Abdomen Analysis is an application that can perform volume calculation for pulmonary nodes, display of low absorption areas, and other analysis for Lung contrasted and non-contrasted CT volume date. In addition, the application can calculate the area and volume (3D) of subcutaneous fat and visceral fat using abdomen CT images. The result can be displayed as a graph, and the fat quantity at each slice position can be presented.

Synapse 3D Lung and Abdomen Analysis is used in addition to the previously-cleared features available from Synapse 3D Basic Tools (K101662) to analyze the images acquired from CT. Synapse 3D Lung and Abdomen Analysis is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting, and treatment planning and accepts DICOM compliant medical images.

Synapse 3D Lung and Abdomen Analysis with Synapse 3D Basic Tools can be integrated with our cleared Fujifilm's Synapse Workstation, version 3.2.1 and above, and can be used as a part of a Synapse system. Synapse 3D Lung and Abdomen Analysis also can be integrated with Fujifilm's Synapse Cardiovascular for cardiology purposes.

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

Indication for Use

Synapse 3D Lung and Abdomen 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 Lung and Abdomen 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 Lung and Abdomen Analysis is intended to;

- use non-contrasted and contrast enhanced computed tomographic images of the lung,

perform boundary detection and volume calculation for pulmonary nodes in the lung based on the location specified by the user and display low absorption areas.

- use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D.

Technological Characteristics

Synapse 3D Lung and Abdomen Analysis 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

Synapse 3D Lung and Abdomen Analysis is tested with reference to its Software Requirements Specification, as documented in Section 16.2 as well as design verification and validation documents and Traceability Matrix document included in this 510(k) filing. Functional testing is a part of the Product Development process, and also included in Section 16 of this filing.

The Synapse 3D Lung and Abdomen Analysis software has undergone Verification and Validation Testing, as described in Section 18. Results: All planned verification and validation tests for Synapse 3D Lung and Abdomen Analysis have passed and the design validation has been successfully completed.

Documentation provided in Section 18 demonstrates that our proposed Synapse 3D Lung and Abdomen Analysis software device is safe and effective and substantially equivalent to the currently-cleared predicate device.

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

Ms. Kimberly A. Sharp
Quality Assurance/Regulatory Affairs Associate
FUJIFILM Medical Systems, USA Inc.
419 West Avenue
STAMFORD CT 06902

MAR 16 2011

Re: K103720
Trade/Device Name: Synapse 3D Lung and Abdomen Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 20, 2010
Received: January 6, 2011

Dear Ms. Sharp:

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 S. Pastel, Sc.D.
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): K103720

Device Name: Synapse 3D Lung and Abdomen Analysis

Indications for Use:

Synapse 3D Lung and Abdomen 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 Lung and Abdomen 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 Lung and Abdomen Analysis is intended to;

- use non-contrasted and contrast enhanced computed tomographic images of the lung, perform boundary detection and volume calculation for pulmonary nodes in the lung based on the location specified by the user and display low absorption areas.
- use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D.

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

510K K103720