K061672

JUN 29 2006

510(k) Summary

Date Prepared

May 12, 2006

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
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Device Trade Name,

Synapse 3D MIP/MPR Image Visualization Software OBLIQUUS

Device Common Name:

Image processing, management and 3D (MIP/MPR) visualization system

Regulation Number:

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 Device

Sectra IDS5 Radiology Workstation with Sectra 3D and MPR packages
510(k) #: K040376, cleared by CDRH on 05/04/04

Description of the Device

Obliquus is an integrated Maximum Intensity Projection (MIP) and Multi-Planar Reformatting (MPR) software package intended to be used with Fuji Synapse Workstation Software Version 3.1.1 and higher. This software is designed to be used by radiologists, clinicians and referring physicians to acquire, process, review, store, print and distribute DICOM compliant image studies utilizing standard PC hardware. Obliquus offers similar user interface and image manipulation functionality as was cleared in Synapse Workstation software version 3.1.0.

The Obliquus software enables the user to display MPR visualization of CT or MRI studies in Synapse. Once opened in Synapse, the images can be presented in the following viewers:

MPR Viewer: Visualizes a study image of the selected series in the following four types of plane images:

(1) Original view is the original CT or MRI study image.

(2) Reformatted A view represents visualization of the original view orthogonal to the original study plane (i.e., if original image is axial, then Reformatted A will be of the coronal plane).

(3) Reformatted B view represents visualization of the original view orthogonal to the original study plane (i.e., if the original image is axial, then Reformatted B will be of the sagittal plane).

(4) Oblique view shows a plane image from any direction specified by the user.

Compare Viewer: Compare viewer consists of four windows and up to four series that can be displayed for visual comparison. The Compare viewer functions are as follows:

- Synchronously display images of each series
- Make synchronous display setting which includes adjusting slice position and changing synchro unit
- Switch among 3 orthogonal plane images
- Set rendering mode and slab thickness
- Display patient study and image information
- Toggle with the MPR viewer

Stereo Viewer: Presents images for stereopsis, particularly for Magnetic Resonance Angiography (MRA) MIP images. The Stereo viewer's functions include:

- Rotating and displaying plane images horizontally
- Setting image display format
- Setting rendering mode, slab thickness and projection angle interval
- Display patient, study and image information
- Toggle with the MPR viewer

Images can be saved either as bitmap files or to the Synapse server.

The maximum allowable number of slices for which images can be visualized depends on the memory capacity of the computer being used. With main memory of 1G bytes, approximately 600 slices of ordinary CT images can be processed.

Software Specifications

Obliquus is optional software for use with the medical network system SYNAPSE version 3.1.1 and higher. To allow Obliquus to run on a PC, it is essential that SYNAPSE is running on that same PC. Specifications for operating this Software are congruous with the SYNAPSE specifications.
Below are notes specific to this Software:

(1) Supported operating systems

Windows 2000 and Windows XP.

(2) Measure of required memory capacity

1 to 2 Gbytes.

Intended Use

Obliquus:

Synapse Image Visualization Software MIP/MPR Obliquus enables the display of 3D (MIP/MPR) visualization of CT and MR studies. Typical users are radiologists, technologists and clinicians.

Predicate Device:

The Sectra IDS5 device is intended for the manipulation and displaying of x-ray images, including mammograms. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

Device options make possible mammography reading, telecommunications; fast demonstration; prosthesis CAD; 3D and angiography, etc.; and teleconferencing.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics

The optional Synapse Image Visualization Software (MIP/MPR) OBLIQUUS is comparable and technically equivalent to the visualization software contained in the Sectra IDS5 device with Sectra 3D and MPR software package in that both are integrated into their PACS workstation and can view 2D images .

Safety Information

Synapse Image Visualization Software (MIP/MPR) Obliquus introduces no new safety or efficacy issues other than those already identified with the predicate device. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of minor concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Testing

Obliquus is tested with reference to its Software Requirements Specifications, as documented in Section 16.3, Traceability Matrix Management included in this 510(k) filing. Functional testing is a part of the Product Development process, also included in Section 16 of this filing.

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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 29 2006

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

Re: K061672
Trade/Device Name: SYNAPSE 3D Visualization Software OBLIQUUS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 13, 2006
Received: June 14, 2006

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Synapse 3D Visualization Software Obliquus**

Indications for Use:

Synapse Image Visualization Software MIP/MPR Obliquus enables the display of 3D (MIP/MPR) visualization of CT and MR studies. Typical users are radiologista, technologists and clinicians.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061671