510(k) Summary
Prepared March 19, 2013

JUL 23 2013

Sponsor: Siemens Medical Solutions, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person: Patrick J. Lynch
Telephone: (650) 694-5658

Submission Date: March 19, 2013

Device Name: eSie Apps Suite

Common Name: System, Image Processing, Radiological

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Picture Archiving and Communications System FR # 892.2050 Product Code 90-LLZ

A. Legally Marketed Predicate Devices

The eSie Apps Suite described in this 510k is substantially equivalent to Siemens fourSight ViewTool, K052895, and to the rendering software used on the Acuson SC2000, K123622.

B. Device Description:

eSie Apps Suite is intended to be the CAP host for 2D and volume imaging applications on a PACS workstation. It is intended to maximize the reuse of the SC2000 renderer for volume display and manipulation. Additionally, the imaging applications from the SC2000 will be redeployed on a PACS workstation for the 2D and volume imaging analysis. Other CAPs will be integrated as the market demands.

eSie Apps Suite is intended to have a simple basic configuration as a PACS plug-in by utilizing the third party launching capability of the host PACS. On the customer's workstation a command line will launch the eSie Apps Suite application – patient context will be shared between the PACS and eSie Apps Suite. Results created by the respective CAPs will be sent back to the PACS for appending to the patient study.

The software level of concern for the eSie Apps Suite is considered moderate.

C. Intended Use

eSie Apps Suite software is intended for use as a PACS plug in utilizing the third party application launching feature of the PACS workstation. eSie Apps Suite software will provide the ability to launch Siemens CAPs (Clinical Application Packages) for image processing. Use of a CAP by a qualified clinician can add information to the study to be used for a clinical diagnosis. This initial release employs one CAP, the eSie Volume Viewer, which provides offline viewing and manipulation of the Acuson SC2000 system volume datasets.

The typical ultrasound user must be knowledgeable in the use of the ultrasound system in order to properly optimize and utilize the software. The eSie Apps Suite software is intended for use on a PACS workstation that must meet minimum system requirements to run optimally and also supports launching of third party applications.

D. Substantial Equivalence

The submission device is substantially equivalent to fourSight ViewTool, previously cleared in K052895, and Acuson SC2000 diagnostic ultrasound system (K123622) image rendering software with regard to both intended use and technological characteristics.

Description	Acuson SC2000™ K123622	fourSight ViewTool K052895	eSie Apps Suite K-TBD
System:			
Medical device software – Software Life Cycle Process - IEC 62304	X	X	X
Application packages:			
syngo® Mitral Valve Assessment	X		
syngo® auto Ejection Fraction technology	X		
D↑ART with syngo® fourSight™ TEE view	X	X	
syngo® Quantitative Synch Tools™ technology (QST)	X		
syngo® Velocity Vector Imaging™ technology (VVI) rotation	X		
syngo® ACQ auto-tracking contrast quantification	X		
Connectivity:			
Wireless Network Connectivity	X		X
DICOM Print Service	X	X	X
DICOM Media Storage Service	X	X	X
DICOM Structured Reporting	X		
Software Features:			
Change the screen display format	X	X	X
SieShell animation displaying the volume as two halves	X		X
Rotate the volume on any axis	X	X	X
Free rotation of the reference plane around any axis	X	X	X
D'art point and click volume manipulation	X	X	X
Secondary clip dynamic or static clip capture to the PACS	X	X	X

E. Performance Data

The eSie Apps Suite is designed, verified, and validated according to the company's design control process and has been subjected to extensive safety and performance testing before release. Final testing of the eSie Apps Suite included various safety and performance testing designed to ensure the device meets all of its specifications including:

- DICOM (Digital Imaging and Communications in Medicine)
- IEC 62304 Medical device software – Software Life Cycle Process

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 23, 2013

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K132062
Trade/Device Name: eSie Apps Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 01, 2013
Received: July 03, 2013

Dear Mr. Job:

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.

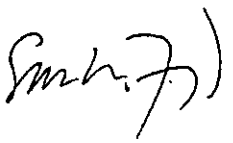
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/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): K132062

Device Name: eSie Apps Suite

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eSie Apps Suite software is intended for use as a PACS plug in utilizing the third party application launching feature of the PACS workstation. eSie Apps Suite software will provide the ability to launch Siemens CAPs (Clinical Application Packages) for image processing. Use of a CAP by a qualified clinician can add information to the study to be used for a clinical diagnosis. This initial release employs one CAP, the eSie Volume Viewer, which provides offline viewing and manipulation of the Acuson SC2000 system volume datasets.

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

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K132062___