K141554

510(k) Summary
Prepared June 5, 2014

JUL 11 2014

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

Contact Person: Shelly Pearce
Telephone: (650) 694-5988

Submission Date: June 5, 2014

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 the company's own device, previously cleared on K132062 and Acuson SC2000, K102017 and K132654.

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.

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.

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 11, 2014

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

Re: K141554
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: June 10, 2014
Received: June 11, 2014

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use

A. 510(k) Number (if known): K141554

Device Name: eSie Apps Suite

Indications for Use:

eSie Apps Suite software is a software-only product to be run on a user's PACS (Picture Archiving and Communication System) workstation. It is intended to launch Siemens CAPs (clinical application packages) for image processing, including the acceptance, transfer, display and digital processing of ultrasound images. Digital processing includes image manipulation and quantification on a workstation. Use of a clinical application package by a qualified clinician can add information to the study to be used for a clinical diagnosis.

The software supports the following clinical application packages:

- eSie Volume Viewer
- eSie LVA
- eSie PISA

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) K141554