Siemens Medical Solutions USA, Inc.   December 10, 2014
℅ Mr. Mark Job
Responsible Third Party Official
1394 25th Street, NW
BUFFALO MN 55313

Re: K143254
    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: November 12, 2014
    Received: November 13, 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,

Robert A Ochs

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)*
K143254

Device Name
eSie Apps Suite

Indications for Use *(Describe)*
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
• eSie Valves

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

5. 510(K) SUMMARY

Submission Date   October 30, 2014

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

Contact Person   Nancy Burke
                       Telephone: (425) 295-8665
                       Fax: (425) 391-9161

Device Name   eSie Apps Suite. Note that for marketing purposes, the names eSie
Apps Suite, syngo® US Apps Suite or syngo® Ultrasound Apps Suite may be used.

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

Legally Marketed Predicate Devices

The eSie Apps Suite as described in this 510k is substantially equivalent to the company's
current legally marketed devices shown below:

Predicate Device	510(k) Number	Clearance Date
eSie Apps Suite	K141554	7/11/2014
ACUSON SC2000 Diagnostic Ultrasound System Software	K142628	10/10/2014

4. Device Description:

eSie Apps Suite is intended to be the Clinical Application Package (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.

5. Intended 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
- eSie Valves

6. Technological Characteristics as Compared to Predicate Devices

The eSie Apps Suite software in this submission is essentially equivalent to the cleared eSie Apps Suite software (K141554). eSie Apps Suite software is activated on a workstation connected to a cardiology PACS that includes a third-party application launcher. It is a graphical launch pad designed to provide viewing, manipulation and quantification functionality for ACUSON SC2000 ultrasound image data sets using Clinical Application Packages (CAPS).

The analysis packages included in this release of eSie Apps Suite are essentially the same as those available in the software on the ACUSON SC2000 Ultrasound System (K142628), except that the eSie Apps Suite CAPS are limited to eSie Volume Viewer, eSie LVA, eSie PISA, and with this submission, eSie Valves.

Feature / Characteristic	eSie Apps Suite	eSie Apps Suite (Primary Predicate)	ACUSON SC2000 Ultrasound System
510(k) Reference	This submission	K141554	K142628
Product Code(s)	LLZ	LLZ	IYN, IYO, ITX, OBJ

(Table continued on next page)

Feature / Characteristic	eSie Apps Suite	eSie Apps Suite (Primary Predicate)	ACUSON SC2000 Ultrasound System
Indications for Use Statement	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 • eSie Valves	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	The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
Display, Measurement and Calculation Packages			
Viewing and manipulation of volume datasets	eSie Volume Viewer	eSie Volume Viewer	Yes
2D quantitative tool for assessment of global and regional myocardial mechanics	N/A	N/A	eSie VVI
3D Left Ventricle volume quantitative analyses (Single + Multibeat)	eSie LVA	eSie LVA	eSie LVA

Feature / Characteristic	eSie Apps Suite	eSie Apps Suite (Primary Predicate)	ACUSON SC2000 Ultrasound System
Quantification of proximal isovelocity surface area	eSie PISA	eSie PISA	eSie PISA 3D semi automatic
2D Automated tool to identify and measure contours of left ventricle and atrium from transthoracic exams	N/A	N/A	eSie Left Heart
Visualize and quantify mitral and aortic valve anatomy	eSie Valves	N/A	eSie Valves

7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

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

8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the eSie Apps Suite in this submission use the same technology and principles as existing devices, clinical data is not required.

9. Conclusion

As shown by the device comparison table above, the modified eSie Apps Suite software has the same intended use as the predicate device, incorporates technological features of the predicate devices cleared through premarket notification and testing indicates that no new issues of safety or effectiveness are raised.