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

September 5, 2014

Siemens Medical Solutions USA, Inc.
% Patricia Jones
Technical Regulatory Specialist
51 Valley Stream Parkway, D-02
MALVERN, PA 19355

Re: K141574
Trade/Device Name: Artis zee/zeego SW VC21
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, IZI, JAK
Dated: August 5, 2014
Received: August 6, 2014

Dear Ms. Jones:

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 and Part 809); 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 and Part 809), 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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Artis zee and Artis zeego

Indications for Use *(Describe)*

Artis zee / zeego is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis zee / zeego family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

Artis zee / zeego can also support the acquisition of position triggered imaging for spatial data synthesis.

The Artis zee and Artis zeego include also the software option DynaCT which identifies the Artis as a system with a C-arm CBCT functionality.

DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

510(k) Summary: Artis zee/zeego - Modular Angiographic System

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: August 5, 2014

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany
Establishment Registration Number:
2240869

2. Contact Person:

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

1. Device Name and Classification:

Trade Name:	Artis zee and Artis zeego - Modular Angiographic System
Classification Name:	Image-Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA, IZI
Secondary Product Code:	JAK

2. Legally Marketed Primary Predicate Device

Trade Name:	Artis zee/zeego with CSX-10 Detector VC21
510(k) Clearance	K122644
Clearance Date	May 16, 2013
Classification Name:	Image-Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA, IZI
Secondary Product Code:	JAK

Legally Marketed Secondary Predicate Device

Trade Name:	Artis Q and Q.zen – Modular Angiographic System
510(k) Clearance	K123529
Clearance Date	February 26, 2013
Classification Name:	Image-Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600 & 21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA, IZI
Secondary Product Code:	JAK

3. Device Description:

/zeego Modular Angiography System is designed as a set of components that may be combined into different configurations to provide specialized angiography systems. This submission contains Quantitative CARE claims to be added.

The Artis zee / zeego Modular Angiography System with the Quantitative CARE claims is the same Angiography System cleared in 510(k) K122644 with the addition of CARE Claims cleared in 510(k) K123529 the Artis Q and Artis Q.zen Modular Angiography systems. All components are described in the Device Description **Section 10** and the Substantial Equivalence **Section 11**.

The intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).

4. Indication for Use:

Artis zee / zeego is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis zee / zeego family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

Artis zee / zeego can also support the acquisition of position triggered imaging for spatial data synthesis.

The Artis zee and Artis zeego include also the software option DynaCT which identifies the Artis as a system with a C-arm CBCT functionality.

DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

5. Substantial Equivalence:

The Artis zee / zeego Modular Angiography System with the Quantitative CARE claims is the same as the legally marketed device and substantial equivalent to Artis zee / zeego Modular Angiography System with CSX-10 Panel detector as listed below. The quantitative CARE claims are the same that have been cleared with Artis Q and Artis Q.zen.

Table 5: Predicate Devices

510(k) Number	Date of Clearance	Device Name
Primary Predicate K122644	May 16, 2013	Artis zee/zeego with CSX-10 Detector
Secondary Predicate K123529	February 26, 2013	Artis Q and Artis Q.zen

6. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

Artis zee / zeego Modular Angiography System is designed as a set of components (C-arm, X-ray tube and housing, flat detector, digital imaging system, collimator, generator etc.) that may be combined into different configurations to provide specialized angiography systems. All of the components used with Artis zee / zeego are the same as used with the current available Artis zee/zeego (K122644). The Quantitative CARE claims of the Artis zee/zeego are the same as cleared in 510(k) K123529 (Artis Q and Artis Q.zen) this information is provided in the Device Description.

The components of the subject device have the same technological characteristics as the ones from the predicate device. The technological characteristics do not differ from the predicate device Artis zee/zeego cleared in 510(k) K122644.

The subject device Artis zee/zeego does not affect the indication for use nor the intended use of the device nor does it alter its fundamental scientific technology for the 510(k) cleared predicate device Artis zee/zeego K122644.

7. Non-Clinical Performance Testing

Non-clinical tests were conducted for the Artis zee/zeego configured with software version VC21 during product development. The labeling modifications described in this Premarket Notification are supported with same evidence cleared in the Artis Q./Q.zen 510(k) K123529.

Siemens claims conformance to a signed statement of conformance to performance standards as follows: **IEC 60601-1; 60601-1-1; IEC 60601-1-2; IEC 60601-1-3; IEC 60601-1-4 ; IEC 60601-2-43; AAMI ANSI ISO 10993-1. IEC ISO-14971 and NEMA PS 3.1 - 3.20 (2011)**

Software documentation for a Major Level of Concern per FDA's Guidance Document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" issued on May **11, 2005** is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted on the Artis zee/ Artis zeego software during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

EMC/electrical safety was evaluated according to the **IEC** standards.
Siemens certify to conform to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate devices in terms of safety and effectiveness. **All** testing and validation have been completed.

Clinical testing was not applicable as the Artis zee/ Artis zeego has no new indication for use nor were new clinical applications introduced to the system.

8. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray images.

9. Conclusion as to Substantial Equivalence:

The Artis zee / zeego Modular Angiography System with Quantitative CARE claims have the same indication for use as the predicate device Artis zee / zeego with software VC21. The addition of the Quantitative CARE claims were cleared in the Artis Q and Q.zen 510(k) K123529.

The functionality of Artis zee / zeego Modular Angiography System is the same as the predicate device. It is Siemens opinion, that the Artis zee / zeego Modular Angiography System VC21 is substantially equivalent to the Artis zee / zeego VC21 Modular Angiography System (K122644) and the Quantitative CARE claims is substantially equivalent to the Artis Q and Artis Q.zen Modular Antiography System (K123529)..