Siemens Medical Solution USA, Inc.
% Ms. Patricia Jones
Sr. Regulatory Affairs Specialist
40 Liberty Boulevard 65-1A
MALVERN PA 19355

August 15th, 2018

Re: K181407
Trade/Device Name: Artis zee/zeego & Artis Q/Q.zen
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, IZI, JAA, JAK
Dated: May 26, 2018
Received: May 30, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

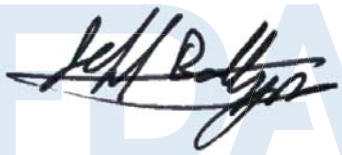
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181407

Device Name
Artis zee / zeego & Artis Q / Q.zen

Indications for Use *(Describe)*
Artis 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 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 can also support the acquisition of position triggered imaging for spatial data synthesis.

The Artis systems include also the software option DynaCT with following IFU:

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SIEMENS

510(k) Summary: Artis zee / zeego & Artis Q / Q.zen

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: August 15, 2018

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 USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Establishment Registration Number: 2240869

Manufacturing Site:
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number: 3004977335

2. Contact Person:

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Phone: (610) 448-6474
Email: patricia.d.jones@siemens-Healthineers.com

3. Device Name and Classification:

Trade Name:	Artis zee / zeego
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, IZI, JAA, JAK
T**rade Name:**	Artis Q and Artis Q.zen
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II

Product Codes: OWB, JAA, IZI

4. Legally Marketed Primary Predicate Device

Trade Name:	Artis zee/zeego SW VC21
510(k) Clearance	K141574
Clearance Date	September 05, 2014
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Codes:	IZI, JAA, JAK
Total Product Life Cycle:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

Legally Marketed Secondary Predicate Device

Trade Name:	Artis Q and Artis Q.zen
510(k) Clearance	K123529
Clearance Date	February 26, 2013
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB,
Subsequent Product Codes:	IZI, JAA
Total Product Life Cycle:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

5. Device Description:

The Artis Modular Angiography systems are specialized angiography systems. In general, they are equipped with C-arm, stand, flat panel detector, x-ray tube, high voltage generator, patient table and image post-processing software.

Siemens currently markets the Artis zee / zeego (K141574) and the Artis Q / Q.zen (K123529). Siemens will provide new software VD11D for both, the Artis zee / zeego and Artis Q / Q.zen systems. The new software VD11D will support the detector Pixium 3040CV (also known as “40HDR”) already cleared with Artis Q / Q.zen (K123529). Systems, Artis zee / zeego, and Artis Q / Q.zen use the cleared AEC (Automatic Exposure Control) functionality.

Siemens intends to market new claims specific to the AEC, which are provided in the product claims list. Siemens will replace the cooling unit in both systems.

The Miyabi Angio-CT configuration has been improved and will be known as and marketed as the nexaris Angio-CT configuration. Siemens nexaris Angio-CT configuration was designed to contain both Angio and CT System within close proximity or within the same environment. The CT-gantry on rails will slide towards the Angiography patient table to perform a CT scan without repositioning the patient. After the CT scan, the CT-gantry could be slide away from the patient table to use the table for Angiography C-arm acquisitions.

This 510(k) submission describes modifications made to the previously cleared predicate devices: Artis zee / zeego SW VC21 (K141574) and Artis Q / Q.zen SW Version VD10 (K123529). The modifications will be marketed as "Artis zee / zeego VD11D" and "Artis Q / Q.zen VD11."

The following modifications/features do not impact any new usage of Contrast Agents.

Proposed Device Modifications for the Artis zee / zeego and the Artis Q / Q.zen Systems:

1. **Revised Indication for Use Statement** applicable to both systems (Artis zee / zeego and Artis Q / Q.zen)
2. **New system software version VD11D** supports hardware for both systems (Artis zee / zeego and Artis Q / Q.zen)
3. **New detector pixium 3040CV** (also known as "as40HDR") Software and Hardware modification applicable to the Artis zee / zeego system only. (This detector is already cleared for use in the Predicate Device for the Artis Q /Q.zen System).
4. N**ew Tube cooling unit** for both systems (Artis zee / zeego and Artis Q / Q.zen)
5. **Product Claims List** - modification applicable for both systems (Artis zee / zeego and Artis Q / Q.zen)
6. **Update 510(k) Information** provided for all predicate devices.

This 510(k) submission also includes the following modification made to the "Miyabi Angio-CT" configuration, which consists of Artis zee / zeego or Artis Q /Q.zen and a CT system (SOMATOM Family Sliding Gantry). The Miyabi Angio-CT configuration that will include these Subject Device modifications will be marketed as "nexaris Angio-CT."

Proposed Device Modifications for the nexaris Angio-CT configuration:

Note: These modifications are only applicable when the Artis zee / zeego or Artis Q / Q.zen and a CT system (SOMATOM Family Sliding Gantry) are

configured in the nexaris Angio-CT configuration. The nexaris Angio-CT is only an environment which may contain an Angio and CT system in close proximity.

7. New software version VD11D interface software component with Angio and CT systems.

- Improved Collision calculation between the Artis zee / zeego or Artis Q / Q.zen and CT Systems.
-

6. Indications for Use:

Artis zee / zeego Indications for Use Statement:

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

The Artis systems include also the software option DynaCT with following IFU:

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.

Artis Q / Q.zen Indications for Use Statement:

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

The Artis systems include also the software option DynaCT with following IFU:

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.

7. Substantial Equivalence:

The Artis zee / zeego and Artis Q / Q.zen SW VD11D is substantially equivalent to the legally marketed predicates listed in the table below:

Table 1: Predicate Comparable Properties

This Tradition Bundled 510(k) Submission Contains Two Angiographic Systems			
Artis zee / zeego VD11D comparable properties:			
Predicate Device Name and Manufacturer	**510(k) Number**	**Clearance Date**	**Comparable Properties**
Primary Predicate Artis zee/zeego SW VC21	K141574	09/05/2014	• Indications for use • System for Image Acquisition • System for post-processing
Secondary Predicates Artis Q and Q.zen - Modular Angiographic System	K123529	02/12/2013	• Detector Pixium 3040CV (as40HDR) • Product Claims
Artis Q / Q.zen VD11D comparable properties:			
Primary Predicate Artis Q and Q.zen - Modular Angiographic System	K123529	02/12/2013	• Indications for use • System for Image Acquisition • System for post processing • Detector Pixium 3040CV (as40HDR) • Product Claims

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

Artis zee / zeego and Artis Q / Q.zen Systems are designed as a set of components (C-arm, X-ray tube and housing, flat panel detector, digital imaging system, collimator, generator etc.) that may be combined into different configurations to provide specialized angiography systems. Components used with Artis zee / zeego and Artis Q / Q.zen are either commercially available with current Siemens systems or include modifications to existing components. Technological differences between the Subject Device and the Predicate Device are provided in the table below for all modifications.

Table 2: Comparison of Technological Characteristics

Modification	Subject Device Artis zee / zeego Angiography System w/SW VD11D	Primary Predicate Device Artis zee/zeego SW VC21 (K141574)	Secondary Predicate Device Artis Q and Artis Q.zen Modular Angiography System VD10 (K123529)	Comparison Results
Indications For Use Statement	IFU statement revised to simplify and improve clarity of content.	Cleared IFU Statement for K141574	**Not applicable**	See row below for results
Comparison Result	The revised IFU statement is within the scope of the Intended Use for Interventional fluoroscopic X-Ray Systems per 21 CFR §892.1650. The minor modification of the cleared IFU statement has no impact on the intended use of the device.			
Software Version	New Software VD11D supports Artis zee / zeego System with Pixium 3040CV 30cm x 40cm 16 bit detector also known as (as40HDR)	Software VC21 for Artis zee/zeego	**Not applicable**	Compatible for both Artis zee / zeego and Artis Q / Q.zen systems meets criteria as tested per Software and SSIX Guidance
Flat Panel Detector	Pixium 3040CV (as40HDR) 30cm x 40cm 16 bit	**Not applicable**	Pixium 3040CV 30cm x 40cm 16 bit also known as (as40HDR)	Same detector as cleared with Artis Q / Q.zen will be used with Artis zee / zeego meets criteria as tested per Software and SSIX Guidance

Tube Cooling Unit	New Tube Cooling Unit: SMC Tube one for all	Tube Cooling Unit: Kluever cooling unit or Lytron cooling system.	**Not applicable**	Same functionality

Modification	**Subject Device Artis Q / Q.zen Systems with SW VD11D**	**Primary Predicate Device Artis Q and Artis Q.zen Modular Angiography System VD10 (K123529)**	**Comparison Results**
Indications For Use Statement	IFU statement revised to simplify and improve clarity of content.	Cleared IFU Statement for K123529	See row below for results
Comparison Result	The revised IFU statement (applicable to both Artis zee / zeego and Artis Q / Q.zen systems) fall within the scope of the Intended Use for Interventional fluoroscopic X-Ray Systems per 21 CFR §892.1650. The minor modification of the cleared IFU statement has no impact on the intended use of the device.		
Software Version	New Software VD11D supports Artis zee / zeego System with Pixium 3040CV 30cm x 40cm 16 bit detector also known as (as40HDR)	Software Version VD10 cleared with Artis Q / Q.zen	Compatible for both Artis zee / zeego and Artis Q / Q.zen systems meets criteria as tested per Software and SSIX Guidance
Tube Cooling Unit	New Tube Cooling Unit: SMC Tube one for all	Lytron cooling unit	Same functionality

Miyabi Angio CT Configuration new marketing name is the nexaris Angio-CT Configuration which is an environment configured with Angio – CT Systems in close proximity previously marketed as Miyabi Angio CT.

Modifications	**Subject Device Configuration nexaris Angio-CT Configuration with Artis zee / zeego or Artis Q / Q.zen**	**Predicate Device Configuration Miyabi Angio CT Configuration with Artis zee / zeego**	**Predicate Device Configuration Miyabi Angio CT Configuration with Artis Q / Q.zen.**	**Comparison Results**
Miyabi Angio-CT System Configuration	New nexaris Angio CT Configuration with Artis zee / zeego or Artis Q / Q.zen Systems	Miyabi Angio CT Configuration with Artis zee / zeego	Miyabi Angio CT Configuration with Artis Q / Q.zen	New marketing name for the previous Miyabi Configuration will be known as the nexaris Angio-CT Configuration with the Artis zee / zeego or Artis Q / Q.zen system and CT Systems with sliding gantry.

Collision Calculation	Collision calculation **(Smart Collision)** of the CT gantry now is based on a CT model	Collision calculation of the CT gantry is based on a simulated moving wall	Collision calculation of the CT gantry is based on a simulated moving wall	Collision calculation has been improved and meets criteria as tested per Software

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for Artis zee / zeego and Artis Q / Q.zen during product development.

The Artis zee / zeego and Artis Q / Q.zen were certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance and Electromagnetic Compatibility:

- ES60601-1:2005/(R)2012
- 60601-1-2:2007
- 60601-1-3:2008
- 60601-1-6:2010/A1:2013
- 60825-1:2007
- TR 60878:2015
- 62304:2006
- 80001-1:2010
- 60601-2-28:2010
- 60601-2-43:2010
- 60601-2-54:2009/A1:2015
- 10993-1:2009
- 14971:2007

Table 3: FDA Guidance Documents

FDA Guidance Document and Effective Date	
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)** Document issued on October 2, 2017
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** Document issued on January 30, 2018
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
4.	Guidance for Industry and FDA Staff: **Deciding when to submit a 510(k) for a change to an existing device.** Document issued on October 25, 2017
5.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** Document Issued on July 28, 2014
6.	Guidance for Industry and FDA Staff: **Guidance for the Submission Of 510(k)'s for**

	Solid State X-ray Imaging Devices Document issued on September 1, 2016
7.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices** Document issued on May 11, 2005
8.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** Document issued on September 9, 1999
9.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**. Document issued February 3, 2016
10.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.** Document issued on November 28, 2017
11.	Guidance for Industry and FDA Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical devices.** Document issued on October 2, 2014
12.	Guidance for Industry and FDA Staff: **Bundling Multiple Devices or Multiple Indications in a Single Submission**. Document issued on June 27, 2007

Verification and Validation:

Software Documentation for a Major Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. The modifications of the Artis zee / zeego and Artis Q / Q.zen, software version VD11D are supported with non-clinical information that demonstrates the software safety through verification and validation testing. Verification and validation testing demonstrate that Artis zee / zeego and Artis Q / Q.zen perform as intended. The non-clinical test data demonstrate that Artis zee / zeego and Artis Q / Q.zen device performance is comparable to the predicate device. Software supports all old and modified hardware components for both subject devices with respect to the intended use. The testing supports that all software specifications have met the acceptance criteria. The verification and validation testing support the claims of substantial equivalence.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable and do not raise any new issues of safety or effectiveness.

Artis zee / zeego and Artis Q / Q.zen software VD11 was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. The Human Factor Usability Validation showed that Human factors are addressed in the system

tests according to the operator's manual and in clinical use tests with customer report and feedback form.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section, is the required cybersecurity information.

Summary:
Performance tests were conducted to test the functionality of Artis zee / zeego and Artis Q / Q.zen software VD11D. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing and clinical assessment were found acceptable and do not raise any new issues of safety or effectiveness.

10. 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.

11. Conclusion as to Substantial Equivalence:

The predicate devices were cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that the Artis zee / zeego and Artis Q / Q.zen SW VD11D acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data and software validation data demonstrates that the Subject Devices are as safe and effective when compared to the Predicate Devices that is currently marketed for the same intended use.