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

Re: K163286
   Trade/Device Name:  ARTIS pheno
   Regulation Number:  21 CFR 892.1650
   Regulation Name:  Interventional fluoroscopic x-ray system
   Regulatory Class:  II
   Product Code:  OWB, JAA
   Dated:   February 10, 2017
   Received:  February 13, 2017

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); 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.

March 9, 2017
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 Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

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 family include also the software option DynaCT with following indications for use:

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: ARTIS pheno

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

Date Prepared: February 10, 2017

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
Fax: (610) 640-4481
Email: patricia.d.jones@siemens.com

3. Device Name and Classification:
Trade Name: ARTIS pheno
Classification Name: Interventional fluoroscopic X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1650
Device Class: Class II
Primary Product Codes: OWB
Secondary Product Code: JAA

4. Legally Marketed Primary Predicate Device
Trade Name: Artis Q and Artis Q.zen - Modular Angiographic System
510(k) Clearance: K123529
**SIEMENS**

**Clearance Date:** February 12, 2013  
**Classification Name:** Interventional fluoroscopic X-Ray System  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR §892.1650  
**Device Class:** Class II  
**Product Codes:** OWB, JAA, IZI  
**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 zee/zeego with CSX-10 Detector SW VC21  
**510(k) Clearance:** K122644  
**Clearance Date:** May 16, 2013  
**Classification Name:** Interventional fluoroscopic X-Ray System  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR §892.1650  
**Device Class:** Class II  
**Product Code:** OWB  
**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:** syngo Application Software  
**510(k) Clearance:** K162541  
**Clearance Date:** November 16, 2016  
**Classification Name:** System, Image processing, Radiological  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR §892.2050  
**Device Class:** Class II  
**Product Code:** LLZ  
**Total Product Life Cycle:** There are no Recalls for this Predicate Device

**5. Device Description:**  
The ARTIS pheno is a further development of the Artis Q and Artis Q.zen - Modular Angiography System. ARTIS pheno is equipped with C-arm, stand, flat panel detector, x-ray tube, high voltage generator, patient table, and image post processing. syngo Application Software is optional available for the support of dedicated clinical workflows.
The following modifications are made to the cleared Artis Q and Artis Q.zen - Modular Angiography System, software version VD10 which created the Subject Device.

**Proposed Device Modifications:**
1) Newly designed C-arm and stand.
2) Optional Anti-Microbial Coating on surface of C-arm, stand and table
3) Newly designed table.
4) Newly designed tableside control modules (TCM)
5) New Flat Panel detector Canon CSX-30
6) Newly designed collimator for both angiography and cardiology
7) New System Software Version VE10
8) Integration of the post-processing syngo Application Software VD20
9) Preparation for ACUSON Freestyle Elite w. Artis Access
10) Modified image processing
11) Modified dose regulation
12) New Display EIZO MX242W
13) Modified Display Ceiling Suspension
14) Proposed product claims associated with the above device modifications
15) Updated 510(k) information

The ARTIS pheno is substantially equivalent to the Artis Q and Artis Q.zen - Modular Angiography System VD10 with all its components as described in the Device Description, and the Substantial Equivalence sections.

6. **Indication for Use:**
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 family include also the software option DynaCT with following indications for use:

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 pheno is substantial equivalent to the legally marketed predicates listed in the table below:

<table>
<thead>
<tr>
<th>Predicate Device Name and Manufacturer</th>
<th>510(k) Number</th>
<th>Clearance Date</th>
<th>Comparable Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Predicate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Artis Q and Q.zen - Modular Angiographic System | K123529 | 02/12/2013 | • Indications for use  
• System for Image Acquisition  
• System for post processing |
| **Secondary Predicates**               |               |                |                                            |
| Artis zee/zeego w/CSX10               | K122644       | 05/16/2013     | • Detector CSX-10 |
| syngo Application Software            | K162541       | 11/16/2016     | • VD11 Post-Processing Software Features |

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

ARTIS pheno is 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 pheno are either commercially available with current Siemens systems or include modifications to existing components. Technological differences between the Subject Device and the Predicate Device is provided in the table below for all modifications.
<table>
<thead>
<tr>
<th>Modification</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Comparison Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly designed C-arm and stand</td>
<td>Stand with C-arm diameter 100-130cm</td>
<td>Stand with C-arm diameter 90-110cm</td>
<td>Increased C-arm diameter for steeper angulations</td>
</tr>
<tr>
<td>Optional Anti-Microbial Coating on surface of C-</td>
<td>Surface of C-arm, stand and table with Anti-Microbial Paint additive</td>
<td>Surface of C-arm, stand and table without Anti-Microbial Paint additive</td>
<td>Less risks of infection due to Anti-Microbial Paint additive</td>
</tr>
<tr>
<td>arm, stand and table</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newly designed table</td>
<td>Improved patient table up to 280kg / 617lbs patient weight motor-assisted longitudinal and transversal travel in leveled and tilted position</td>
<td>Standard patient table up to 250kg / 550lbs patient weight motor-assisted longitudinal travel in tilted position</td>
<td>Improved patient table due to increased patient load and higher flexibility in positioning</td>
</tr>
<tr>
<td>Newly designed tableside control modules</td>
<td>TCM (Table Control Module)</td>
<td>TCM (Table Control Module)</td>
<td>Newly designed with similar functionality</td>
</tr>
<tr>
<td></td>
<td>PCM (Pilot Control Module)</td>
<td>ECC (Examination Control Console)</td>
<td>Consolidation of tableside controls resulting in reduced distance for operation</td>
</tr>
<tr>
<td></td>
<td>CCM (Collimator Control Module)</td>
<td>CCM (Collimator Control Module)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consolidation of tableside controls resulting in reduced distance for operation</td>
<td>Hygienic optimization due to sealed joysticks, inner dead man switches and less corrugated gaiters.</td>
<td></td>
</tr>
<tr>
<td>New flat panel detector Canon CSX-30</td>
<td>CSX-30 2496 x 1856 pixels for Live 2k imaging</td>
<td>CSX-10 1792 x 1632 pixels with 2x2 binning</td>
<td>Similar resolution with similar input fields</td>
</tr>
<tr>
<td></td>
<td>1024 x 1024 pixels for 1k imaging</td>
<td>896 x 816 pixels with 2x2 binning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Input fields 50 cm, 42 cm, 32 cm, 22 cm, 16 cm, 11 cm</td>
<td>Input fields 39 cm, 32 cm, 26 cm, 20 cm, 16 cm, 10 cm</td>
<td></td>
</tr>
<tr>
<td><strong>Newly designed collimator for both angiography and cardiology</strong></td>
<td>One collimator for both angiography and cardiology</td>
<td>One dedicated angiography and one dedicated cardiology collimator</td>
<td>The newly designed collimator combines the functionality of both the angiography and cardiology</td>
</tr>
<tr>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td><strong>New Software Version VE10</strong></td>
<td>Communication platform for C-Arm, table movements, tableside control modules, detector, collimator, Integration of the syngo Application Software VD20, image processing, dose processing via Profinet protocol (industrial standard)</td>
<td>Communication platform for C-Arm, table movements, tableside control modules, detector, collimator, Interface to the syngo Application Software, image processing, dose processing via CAN protocol (Controller Area Network)</td>
<td>CAN protocol (Controller Area Network) has changed to the Profinet protocol (industrial standard)</td>
</tr>
<tr>
<td><strong>Integration of the post-processing syngo Application Software VD20</strong></td>
<td>syngo Application Software available on ARTIS pheno PC hardware</td>
<td>syngo Application Software available on separate syngo X Workplace or on separate PC hardware</td>
<td>Functionality of syngo Application Software remains the same and runs on one PC hardware</td>
</tr>
<tr>
<td><strong>Preparation for ACUSON Freestyle Ultrasound System Artis Freestyle Access</strong></td>
<td>Preparation for ACUSON Freestyle Ultrasound System Artis Freestyle Access. The interface will allow for viewing of ultrasound images at the Large Display of the Artis system</td>
<td>Preparation for ACUSON Freestyle Ultrasound System Artis Freestyle Access filed via NFJ. The interface will allow for viewing of ultrasound images at the Large Display of the Artis system</td>
<td>Mechanical adaptation for ACUSON Freestyle. Use of existing interface of the ARTIS system</td>
</tr>
<tr>
<td><strong>Modified image processing</strong></td>
<td>-2k image matrix with up to 15f/s - Advanced noise reduction algorithm - Automated contrast and brightness adjustment - spatial modulation transfer function up to 16 frequency bands</td>
<td>-1k image matrix with up to 15f/s - noise reduction algorithm - Manual contrast and brightness adjustment (windowing) --spatial modulation transfer function up to 3 frequency bands</td>
<td>Increased image matrix More precise control of the final image presentation</td>
</tr>
</tbody>
</table>
9. **Nonclinical Performance Testing:**
Non-clinical tests were conducted for ARTIS pheno, during product development.

The ARTIS pheno was 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
- 60825-1:2007
- TR 60878:2015
- 62304:2006
- 80001-1:2010
- 60601-2-28:2010
- 60601-2-43:2010
- 10993-1:2009
- 14971:2007

All tests were passed.

The modifications described in this Premarket Notification were supported with verification and validation testing.

**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 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 were conducted on ARTIS pheno during product development.
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 to support the claims of substantial equivalence.

ARTIS pheno was tested 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 safety relevant functions that need to be revalidated. Further risk mitigations have been defined in a corrective action plan to inform and train the current users of Artis pheno VE10. Users understanding of warnings were founded during testing. Warnings were updated in the documentation and the summative usability validation with two different samples of representative users was performed.

The ARTIS pheno VE10 has been found to be safe and effective for the intended users, uses and use environments, based on the results ascertained at the two clinical use test sites in Frankfurt and Hannover.

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 pheno. 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 device was cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrates that the ARTIS pheno acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data, clinical images and software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Devices that is currently marketed for the same intended use.