Siemens Medical Solution USA, Inc.
c/o Kimberly Rendon
Director, SHS AM NAM QT Regulatory Affairs
40 Liberty Boulevard 65-1A
MALVERN, PA 19355

June 29, 2020

Re: K201156
Trade/Device Name: ARTIS pheno (VE2)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: April 28, 2020
Received: April 30, 2020

Dear Kimberly Rendon:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K201156

Device Name
ARTIS pheno (VE2)

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. This does not include projection radiography.

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.

510(k) Summary: K201156

ARTIS pheno (VE2)

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

Date Prepared: April 28, 2020

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

Kim Rendon
Director, SHS AM NAM QT Regulatory Affairs
Siemens Medical Solutions USA, Inc.

3. Device Name and Classification

Trade Name:	**ARTIS pheno (VE2)**
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, JAA

4. Legally Marketed Primary Predicate Device

Trade Name:	**ARTIS icono (VE2)**
510(k) Number:	K190768
Clearance Date:	September 12, 2019
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Codes:	IZI, JAA, JAK
Total Product Life Cycle:	There are no Recalls nor MDR incidents for this cleared device.

Legally Marketed Secondary Predicate Device 1	
Trade Name:	**ARTIS pheno**
510(k) Number:	K163286
Clearance Date:	March 09, 2017
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB
Subsequent Product Codes:	JAA
Total Product Life Cycle:	*

Legally Marketed Secondary Predicate Device 2	
Trade Name:	**Artis zee/zeego&Artis Q/Q.zen (VD11D)**
510(k) Number:	K181407
Clearance Date:	August 15, 2018
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	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 Development Design Input phase to ensure the latest models will not be affected by any applicable issue.

5. Device Description

The ARTIS pheno (VE2) system is a multi-axis system, specifically designed to meet the growing demands of high-end imaging for interventional radiology, interventional cardiology, minimally invasive and hybrid surgery procedures. The stand allows positioning in angular, orbital, lateral, longitudinal and vertical directions, leveraging the flexible isocenter. The ARTIS pheno (VE2) system is equipped with a robotic multi-axis floor stand, C-arm, flat panel detector, x-ray tube, collimator, high voltage generator, patient table, and image post processing. The ARTIS pheno is partially coated with an optional anti-microbial coating. *syngo* Application Software is optional, available for the support of dedicated clinical workflows.

The ARTIS pheno (VE2) covers the complete range of angiographic applications, cardiac angiography, neuro-angiography, general angiography, surgery and surgical angiography, multipurpose angiography, rotational angiography and radiographic/ fluoroscopic procedures.

1) The following components are configured to create the ARTIS pheno VE2 system: Floor stand with C-arm, X-ray tube assembly and FD
2) Patient table
3) Display ceiling suspension with displays

4) Footswitch for releasing radiation
5) Control console for controlling the stand, patient table, collimator and imaging system.

Images and operating elements are displayed on screens. Different display variants are used to visualize image and information content. Panoramic display configurations or large displays can be used, configurable to visualize multiple images and information content in various layouts.

Post processing can be done in the exam room or in the control room that offers monitors as well, with a footswitch location in the exam room or the control room. The ARTIS pheno (VE2) System is capable of 2D and 3D imaging.

Other systems and software *syngo* Application Software, *syngo* X Workplace, Sensis, and or third-party systems may also be integrated into the ARTIS pheno (VE2) screen configuration. Different screen configurations and layouts are possible in the examination room and in the control room.

The Subject Device, "ARTIS pheno with software version VE2," will support the following categories of modifications made to the Subject Device in comparison to the Predicate Devices:

1) Modified Software

Table 1: Overview - Software Modifications ARTIS pheno VE2 System

NEW System Software Modifications "VE2" (VE20)	
1.	**Modified Indications For Use Statement**
2.	**System Software VE2 (also known as VE20), software modification/features**
3.	**Improved Roadmap** A. Increased image quality dose ratio and faster workflow via new Architecture and Organ Program parametrization due to improved algorithms B. Improved Image Quality due to improved algorithm C. Subtracted fluoro mode: Dose, Time, and Contrast Agent Savings D. Automap Integration in DSA Roadmap Workflow
4.	**OPTIQ - New Marketing Terminology.** "OPTIQ" - marketing name for the following previously cleared features in K190768: 1. CNR based AEC 2. Improved Roadmap features
5.	**3D Imaging -** *syngo* DynaCT Multiphase
6.	**Improved ClearStent Live**
7.	**Updated User Interface (Pilot Module)** A. Case Flow B. "Favorites" in Toolbars in control room C. Direct position buttons to save and recall the positions of the C-arm D. C-arm swivel buttons on the side of the joystick, instead of next to the joystick
8.	**Generic Interface for 3rd parties for data transference**

2) Modified Hardware/Software

Table 2: Overview – Hardware/Other Modifications ARTIS pheno VE2 System

Hardware/Other Modifications ARTIS pheno VE2 System	
	Device Hardware Modifications
9.	**New Flat Panel Detector Trixell 3040CV (as known as as40HDR)**
10.	**New Optional Touch Control Displays**
11.	**New Variations of Display Ceiling Mounts** A. DCS-2x32'' Pivot (fixed) mounted or rail (movable) mounted Improved Image Quality due to improved algorithm B. Large Display DCS with up to two (2) additional (Artis) displays on the rear side; or one (1) additional (Artis) display and one (1) ACUSON Freestyle display/system on the rear side
12.	**New 3rd Party Accessory Heatable Mattress**
13.	**Additional Video Interface Inputs**
14.	**Updated Cockpit Solution**
	Other Device Modifications
15.	**Product Claims for the ARTIS pheno VE2 (VE20)**
16.	**Update 510(k) Information**

6. 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. This does not include projection radiography.

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 systems also include the software option DynaCT with the 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 (VE2) system is substantial equivalent to the legally marketed predicates listed in **Table 3** below:

Table 3: Predicate Device Comparable Properties for Subject Device Modifications

Predicate Device Name (all Siemens)	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate **ARTIS Icono (VE2)**	K190768	9/12/2019	• Indications for use • Software Version VE2 • Roadmap • OPTIQ (Marketing terminology) • 3D Imaging – syngo DynaCT Multiphase • ClearStent Live + • User Interface - Case Flow • Generic Interface - 3rd party data transference • 3rd Party Accessory Heatable Mattress • Optional Touch Control Displays • Variations of Display Ceiling Mounts • Video Interface Inputs • ARTIS Cockpit Solution
Secondary Predicates **ARTIS pheno**	K163286	3/09/2017	• Pilot Module • ARTIS Cockpit Solution
Artis zee/zeego (VD11D)/Artis Q/Q.zen	K181407	8/15/2018	• Flat Panel Detector 3040CV (aka - (as40HDR))

8. Summary of Technological Characteristics of the Subject Device, Compared to the Predicate Device

The ARTIS pheno (VE2) System is designed as a set of components (floor stand, C-arm, X-ray tube and housing, flat panel detector, digital imaging system, collimator, generator, etc.) that is combined to provide a specialized angiography system. Components used with ARTIS pheno (VE2) System 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 4** below for all modifications.

Table 4: Summary of Comparison of Technological Characteristics

	Subject Device SW Modifications ARTIS pheno (VE2) System	Comparison Results to the Predicate
1.	**Modified Indications for Use Statement**	**Same** as Primary Predicate – K190768
2.	**ARTIS pheno System (VE2) SW Modifications**	**Same** as Primary Predicate – K190768 The Subject Device software modifications (numbers: **2. – 7.B.)** are the same software modifications as cleared in the Primary Predicate - K190768. There are no technological differences

		in the listed modifications when compared to the Primary Predicate Device**.**
3.	**Improved Roadmap** A. Increased image quality dose ratio and faster workflow via new Architecture and Organ Program parametrization due to improved algorithms B. Improved Image Quality due to improved algorithm C. Subtracted fluoro mode: Dose, Time, and Contrast Agent Savings D. Automap Integration in DSA Roadmap Workflow	Same as 2.
4.	**OPTIQ** - New Marketing Terminology. "OPTIQ" - marketing name encompassing the following previously cleared features in K190768. 1. CNR based AEC 2. Improved Roadmap features	Same as 2.
5.	**3D Imaging -** *syngo* DynaCT Multiphase	Same as 2.
6.	**Improved ClearStent Live**	Same as 2.
7.	**Updated User Interface (Pilot Module)** A. Case Flow B. "Favorites" in Toolbars in control room C. Direct position buttons to save and recall the positions of the C-arm D. C-arm swivel buttons moved to the side of the joystick, instead of being next to the joystick	**7.C. Exactly the same** as Primary Predicate – K190768 **7.D. Modified** button location only. Moved buttons from sitting next to the joystick, to the side of the joystick. **Same** button functionality as Secondary Predicate, ARTIS pheno K163286.
8.	**Generic Interface for 3rd parties for data transference**	**Exactly the same** system software features as the Primary Predicate – K190768.
	Hardware/Software Modifications	
9.	**New Flat Panel Detector Trixell 3040CV (aka - as40HDR)**	**Exactly the same detector** as cleared in Secondary Predicate – K181407. There are no technological differences in the Flat Panel Detector 3040CV.
10.	**New Optional Touch Control Displays**	**10. – 12. Exactly the same** modifications as cleared with the Primary Predicate – K190768. There are no technological differences in the listed modifications when compared to the Primary Predicate device.
11.	**New Variations of Display Ceiling Mounts** A. DCS-2x32'' Pivot (fixed) mounted or rail (movable) mounted Improved Image Quality due to improved algorithm B. Large Display DCS with up to two (2) additional (Artis) displays on the rear side; or one (1) additional (Artis) display and one (1) ACUSON Freestyle display/system on the rear side	Same as 10.

12.	**New 3rd Party Accessory Heatable Mattress**	Same as 10.
13.	**Additional Video Interface Inputs**	**Same** number of external video inputs and the same functionality as the primary predicate – K190768.
14.	**Updated Cockpit Solution**	**Modified:** The architecture/hardware has changed. The hardware is now integrated into the system's own image system cabinet and not realized via 3rd-party component. The functionality is same as the Secondary Predicate Device.
	Other Device Modifications	
15.	**Product Claims for the Artis pheno (VE20)**	Device claims with supporting information is included in this submission.
16.	**Update 510(k) Information**	Update 510(k) (changes to the Predicate Device since clearance) are included this submission.

9. Nonclinical Performance Testing

Non-clinical tests were conducted for the ARTIS pheno (VE2) during product development.

The ARTIS pheno (VE2) was certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance and Electromagnetic Compatibility:

- AAMI ANSI ES60601-1:2005/(R)2012
- IEC 60601-1-2:2014
- IEC 60601-1-3:2013
- IEC 60601-1-6:2010/A1:2013
- IEC 60825-1:2007
- TR 60878:2015
- IEC 62304:2015
- IEC 80001-1:2010
- IEC 60601-2-28:2017
- IEC 60601-2-43:2017
- IEC 60601-2-54:2009/A1:2015
- ISO 10993-1:2009
- ISO 14971:2007
- IEC 62366-1:2015

Table 5: 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 September 13, 2019**
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff Document issued on September 13, 2019**
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 27, 2019**
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: **Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medical Devices. Document issued on September 14, 2018**
13.	Guidance for Industry and FDA Staff: **Medical Device Accessories - Describing Accessories and Classification Pathways. Document issued on December 20, 2017**
14.	Guidance for Industry and FDA Staff: **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions. Document issued on December 20, 2019**

The modifications described in this Premarket Notification are 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 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. Non-clinical tests were conducted on ARTIS pheno System software (VE2) 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 the verification and validation for the device was found acceptable to support the claims of substantial equivalence.

ARTIS pheno System software (VE2) 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 test according to the operator's manual and in clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

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. Compliance with IEC 80001-1-2010 is the responsibility of the hospital. Provided in the Software Section is the required cybersecurity information.

Nonclinical Testing Summary

Performance tests were conducted to test the functionality of ARTIS pheno (VE2) System. 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 pheno (VE2) System 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 Device is as safe and effective when compared to the Predicate Devices that is currently marketed for the same intended use.