June 29, 2022

Siemens Medical Solutions USA, Inc.
% Patricia Jones
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN PA 19355

Re: K220409
Trade/Device Name: ARTIS pheno (VE21) System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: June 15, 2022
Received: June 17, 2022

Dear Patricia 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/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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220409

Device Name
ARTIS pheno (VE21) System

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.

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

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510(k) Summary: ARTIS pheno (VE21)

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

Date Prepared: June 28, 2022

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
   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
   Regulatory Affairs Professional
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard, 65
   Malvern, PA 19355
   Phone: (678) 575-8832
   Email: patricia.jones@siemens-Healthineers.com

3. **Device Name and Classification:**

Trade Name:	**ARTIS pheno (VE21)**
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 pheno (VE20)**
510(k) Clearance	K201156
Clearance Date	June 29, 2020
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 Code :	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 pheno (VE21) 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 (VE21) 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 (VE21) 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.

The following components are configured to create the floor configuration:
(1) 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 (VE21) 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 (VE21) screen configuration. Different screen configurations and layouts are possible in the examination room and in the control room.

The 510(k) submission, Subject Device "ARTIS pheno with software version VE21" will support the following modifications made to the Subject Device in comparison to the Predicate Device:

Table 1. Modifications for ARTIS pheno (VE21) System

Software/Hardware modifications specific to New System Software VE21
1. Updated system Software from VE20 to VE21
A. NOMSIE DSA (IQ Customization of Contrast in DSA images
B. Optional New Generator
2. Updated 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 also include 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 (VE21) system is substantial equivalent to the legally marketed predicate listed in the **Table 2** below:

Table 2: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate	K201156	06/29/2020	• Indications for use • Software Version VE20 • Image Quality • Generator
ARTIS pheno (VE20)			

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

The ARTIS pheno (VE21) 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 (VE21) 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 3** below for all modifications.

Table 3: Summary of Comparison of Technological Characteristics

Modifications	Subject Device ARTIS pheno (VE21)	Predicate Device ARTIS pheno (VE20) K201156	Comparison Results
New System Software Changes	1. Updated system Software from VE20 to VE21	System Software Version VE20	**Comparable:** System software VE21 was updated to support NOMSIE DSA (IQ) Customization of Contrast in DSA Images and a new Generator. System Software modifications conforms to "Guidance for the content of Premarket submission for software in Medical Devices". Provided is all required software testing. Provided in this submission are Bench Test Summaries. These software and hardware changes do not raise any new risks or any issues regarding the safety nor effectiveness of the device. All test results met all acceptance criteria.
	A. NOMSIE DSA (IQ) Customization of Contrast in DSA Images	Classical edge enhancement with filters and automatic windowing was used.	
	B. Optional New Generator (Polydoros ACX)	Generator (Polydoros A100G)	
Update 510(k) Information	2. Updated 510(k) information for the Primary Predicate Device is provided.		

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the ARTIS pheno (VE21) during product development.

The ARTIS pheno (VE21) 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

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

Verification and Validation:

Software Documentation for a Moderate 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 (VE21) 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 System software (VE21) 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. 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. 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 (VE21) 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 (VE21) 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.