December 14, 2023

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

Re: K230950
Trade/Device Name: ARTIS icono (VE30A)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, IZI, JAA, JAK
Dated: November 30, 2023
Received: December 1, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K230950

Device Name
ARTIS icono (VE30A)

Indications for Use *(Describe)*
ARTIS is a family of dedicated angiography systems developed for single-plane 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.

The ARTIS systems can also support the acquisition of position triggered imaging for spatial data synthesis.

The ARTIS systems 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: ARTIS icono (VE30A)
510(K) #: K230950

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

Date Prepared: December 7, 2023

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

3. **Device Name and Classification:**

Trade Name:	**ARTIS icono (VE30A)**
Classification Name:	Image-intensified fluoroscopic X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, IZI, JAA, JAK

4. **Legally Marketed Primary Predicate Device:**

Trade Name:	**ARTIS icono (VE21)**
510(k) Clearance	K220432
Clearance Date	June 29, 2022
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 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 icono (VE30A) is a medical device that allows visualization of vessels within the human body. It is of the utmost importance to find the right projections so physicians can navigate catheters and other devices safely. The ARTIS icono (VE30A) consists of a patient table and a multi-axis motorized c-arm that can be positioned around the patient and angulated in a double-oblique fashion iso-centering the region of interest between the x-ray tube and the flat panel detector. The X-ray generator is placed separately. The displays for visualizing the X-ray images are mounted at the ceiling with a movable display suspension system. System operation is executed via control modules table side so that the physician can move and position the table and c-arm adequately for best imaging while manipulating catheters or other devices during the x-ray. X-ray release is tableside via a footswitch.

The ARTIS icono (VE30A), modular angiography systems are designed as sets of components that may be combined into two different configurations (Biplane or Floor) to provide specialized angiography systems. In general, they are equipped with a C-arm, stand, flat panel detector, x-ray tube, collimator, high voltage generator, patient table, and image post-processing.

The ARTIS icono (VE30A) covers the complete range of angiographic applications, cardiac angiography, neuro-angiography, general angiography, surgery and surgical angiography, multipurpose angiography, rotational angiography, radiographic/fluoroscopic procedures.

The following components are configured to create a Floor or Biplane 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, and imaging system

Images and operating elements are displayed on screens. Depending on the ARTIS icono (VE30A) configuration, different display variants are used to visualize image and information content. Displays that visualize single images or large displays that are configurable to visualize multiple images and information contained in various layouts are used.

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 icono (VE30A) is capable of 2D and 3D imaging. The c-arms can be mounted on the floor or for biplane systems on the floor and the ceiling. Other systems and software *syngo* Application Software, *syngo* X Workplace, Sensis, and or third-party systems may also be integrated into the ARTIS icono (VE30A) screen configuration. Different screen configurations and layouts are possible in the examination and control rooms.

The Subject device ARTIS icono with software version VE30A supports the following modifications.

Table 1: Modification for ARTIS icono (VE30A)

Software / Hardware changes specific to New System Software VE30A
1. Updated system Software from VE21A to VE30A
A. Added an optional Second Workplace
B. Updated memory data storage to 600K
C. Updated of Roadmap Phase 3
D. Added new elements for Organ Program “Structure Scout”: Calcium, Gadolinium, and Bismuth
E. Updated Usability Features:
1) Updated Case Flow feature to include Editing
2) Updated Body Region to include Editing
3) Updated Procedure Name to include Editing
4) On Screen Display Reconfiguration
5) Updated Favorites on the Pilot Module to include protocols, frame, and pulse rates
6) Updated Direct Access Bar on the Pilot Module to include Editing
7) Updated Favorite on the Pilot Module to include List & Icon View
8) Updated ARTIS Profiles to include User Profile
9) Updated Pilot Module to lock
10) Updated Image Directory to include Custom Filter possible as default
11) Additional Display Layouts for Cockpit
12) Added “Inactive” as a function for Dynamic Viewer during PT registration and after system restarts.
2. New PC for imaging System due to obsolescence

6. Indications for Use:

ARTIS is a family of dedicated angiography systems developed for single-plane 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.

The ARTIS systems can also support the acquisition of position triggered imaging for spatial data synthesis.

The ARTIS systems 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 icono (VE30A) is substantially equivalent to the legally marketed predicate listed in the table 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	K220432	06/29/2022	• Indications for use • Software Version VE21 • PC • Usability Features • Workplace Station • Data Memory Storage • Roadmap Feature • Structure Scout
ARTIS icono (VE21) Siemens			

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

The ARTIS icono (VE30A) is designed as a set of components (C-arm, X-ray tube, housing, flat panel detector, digital imaging system, collimator, generator, etc.) that may be combined into two different configurations (Floor & Biplane to provide specialized angiography systems. Components used with ARTIS icono (VE21) 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 **Table 3** below for all modifications.

Table 3: Summary of Comparison of Technological Characteristics

Modifications	Subject Device ARTIS icono (VE30A)	Predicate Device ARTIS icono (VE21A) K220432	Comparison Results
New System Software/ Hardware Changes	1. Updated system Software from VE21A to VE30A	System software version VE21	**Comparable:** System software VE30A was updated to support modifications 1A – 2. All System Software modifications conform to "Guidance for the content of Premarket submission for software in Medical Devices" These software and hardware changes do not raise any new risks or any issues regarding the safety or effectiveness of the device. All test results met all acceptance criteria.
	A. Added an optional 2nd Workplace	ARTIS icono offered only 1 Workplace	
	B. Updated memory data storage to 600K	Memory data storage is 400K	
	C. Updated Roadmap Phase 3	Roadmap with 4 phases	
	D. Added new elements for Organ Program "Structure Scout": Calcium, Gadolinium, and Bismuth	Structure Scout cleared elements are platinum, tantalum, iron, iodine, steel and nitinol, and CO2	
	E. Updated Usability Features:		
	1) Updated Case Flow feature to include Editing	Editing of the Case Flow was not available.	
	2) Updated Body Region to include Editing	Editing of the Body Region was not available.	
	3) Updated Procedure Name to include Editing	Editing of the Procedure Name was not available.	
	4) On Screen Display Reconfiguration	Reconfiguring of the On-Screen Display was not available.	
	5) Updated Favorites on the Pilot Module to include protocols, frame and pulse rates	Favorites on PM did not include protocols, frame and pulse rates.	
	6) Updated Direct Access Bar on the Pilot Module to include Editing	Editing of the Direct Access Bar was not available.	
	7) Updated Favorite on the Pilot Module to include List & Icon View	Favorites on PM with list & Icon View was not available.	
	8) Updated ARTIS Profiles to include User Profile	ARTIS Profiles to include user Profile was not available.	
	9) Updated Pilot Module to lock	Locking PM was not available.	
	10) Updated Image Directory to	Image Directory to include Custom Filters as default	

Modifications	Subject Device ARTIS icono (VE30A)	Predicate Device ARTIS icono (VE21A) K220432	Comparison Results
	include Custom Filter possible as default	was Body Region was not available.	
	11) Additional Display Layouts for Cockpit	Additional Display Layouts for cockpits were not available.	
	12) Added “Inactive” as a function for Dynamic Viewer during PT registration and after system restarts.	Dynamic Viewer was Active during PT registration and after system restarts. Inactive was not available.	
New PC	2. New PC for Imaging System due to obsolescence	PC for Imaging System	
	3. NFJ- 0157: Modifications for the ARTIS icono (floor & biplane) for inclusion of the new ARTIS Transfer Solution in combination with MR Nexaris Dockable Table for system MAGNETOM Vida / Sola	NFJ- 0157: Modifications for the ARTIS icono (floor & biplane) for inclusion of the new ARTIS Transfer Solution in combination with MR Nexaris Dockable Table for system MAGNETOM Vida / Sola	
	4. NFJ #0163-Introduction of optional AVVIGO™ Guidance System II to the Artis Family of Medical Devices. The AVVIGO Guidance System II is a 3rd Party 510(k) cleared device (K212490) that is integrated (connected) with the ARTIS system	NFJ #0163-Introduction of optional AVVIGO™ Guidance System II to the Artis Family of Medical Devices. The AVVIGO Guidance System II is a 3rd Party 510(k) cleared device (K212490) that is integrated (connected) with the ARTIS system family	

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the ARTIS icono (VE30A) during product development. The following non-clinical testing was conducted on the presented modifications and relied on: Software functional, verification, and System validation testing with passing results. Configuration, DSA Roadmap, Subtracted Fluoro and transfer images testing was conducted in support of the Updated roadmap Phase 3. CNR image Quality exposure control, fluoro auto exposes values cardiology, DR, CNR, DSA, and neuro testing were conducted for Structure Scout new elements for the Organ program. All testing results passed.

The ARTIS icono (VE30A) 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 60601-1-2:2020
- IEC 60601-1-3:2013
- IEC 60825-1:2014
- TR 60878:2015
- IEC 62304:2015
- IEC 80001-1:2010
- IEC 60601-2-28:2017
- IEC 60601-2-43:2019
- IEC 60601-2-54:2018
- ISO 10993-1:2018
- ISO 14971:2019
- ISO 15223-1:2021
- ISO 17664:2018
- ISO 17664-2:2021
- IEC 60601-2-35:2020
- IEC 62366-1:2020
- IEC 62563-1:2021
- NEMA PS 3.1:2022
- ANSI UL 2900-1:2017
- ANSI UL 2900-2-1:2017
- AAMI TIR57:2016
- ISO 14155:2020

Verification and Validation:
Non-clinical tests were conducted on ARTIS icono System software (VE30A) during product development. The modifications described in this Premarket Notification are supported with verification and validation testing.

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

ARTIS icono (VE30A) 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 the ARTIS icono (VE30A). These tests have been performed to assess the functionality of the subject device. The results of all conducted testing and clinical assessments were found acceptable and did 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 safely and effectively.

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 practices, and all equipment is subject to final performance testing. Furthermore, the operators are healthcare professionals who are trained and responsible for evaluating the post-processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information. Non-clinical test results demonstrate that the ARTIS icono (VE30A) 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 Device that is currently marketed for the same intended use.