April 24, 2026

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

Re: K254173
Trade/Device Name: ARTIS icono floor; ARTIS icono biplane; ARTIS icono ceiling; ARTIS pheno
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: December 23, 2025
Received: March 25, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

GABRIELA M. RODAL -S Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254173

Device Name
ARTIS icono floor; ARTIS icono biplane; ARTIS icono ceiling; ARTIS pheno

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 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.

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 floor**
ARTIS icono ceiling
ARTIS icono biplane
ARTIS pheno

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

Date Prepared: December 23, 2025

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
   Malvern, PA 19355
   Phone: (678) 575-8832
   Email: patricia.jones@siemens-Healthineers.com

3. **Device Name and Classification:**

Trade Name:	**ARTIS icono floor** **ARTIS icono ceiling** **ARTIS icono biplane** **ARTIS pheno**
Classification Name:	Image-intensified fluoroscopic X-ray System
Common Name:	Interventional Fluoroscopic X-Ray System
Classification Panel	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Primary Product Code:	OWB,
Subsequent Product Codes:	IZI, JAA, JAK

4. **Legally Marketed Primary Predicate Device**

Trade Name:	**ARTIS icono (VE40A) (floor)** **ARTIS icono (VE40A) (biplane)** **ARTIS icono (VE40A) (ceiling)** **ARTIS pheno (VE40A)**
510(k) Clearance	K241572
Clearance Date	October 22, 2024
Classification Name:	Image-intensified fluoroscopic X-ray System
Common Name:	Interventional Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Primary 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.

Secondary Predicate

Trade Name:	**Artis zee/zeego & Artis Q/Q/zen**
510(k) Clearance	K181407
Clearance Date	August 15, 2018
Classification Name:	Image-intensified fluoroscopic X-ray System
Common Name:	Interventional Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Primary 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 / ARTIS pheno (VE50B) systems allow 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 / ARTIS pheno (VE50B) systems consist 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 the catheters or other devices during the X-ray. X-ray release tableside via a footswitch.

Both systems 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 / ARTIS pheno (VE50B) systems cover the complete range of angiographic applications, cardiac angiography, neuro-angiography, general angiography, surgery and surgical angiography, multipurpose angiography, rotational angiography, and radiographic/fluoroscopic procedures.

Images and operating elements are displayed on screens. Depending on the ARTIS icono / ARTIS pheno (VE50B) systems 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 content in various layouts are used.

Post-processing can be conducted 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 / ARTIS pheno (VE50B) systems are capable of 2D and 3D imaging.

Other systems and software syngo Application Software, syngo X Workplace, Sensis Vibe, and or third-party systems may also be integrated into the ARTIS icono / ARTIS pheno (VE50B) systems screen configurations. Different screen configurations and layouts are possible in the examination and control rooms.

Siemens Nexaris Angio-CT configuration is designed to contain both 510(k) cleared 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 slide away from the patient table to use the table for Angiography C-arm acquisitions.

The Nexaris Angio-CT (cleared in K181407) configuration has been updated from software version VD11D to VE50B to include additional hardware which prepares communication between a CT sliding gantry and ARTIS VE50B systems enabling collision avoidance by processing position data of both devices.

This 510(k) submission, Subject devices ARTIS icono / ARTIS pheno (VE50B) systems will support the following modifications made to the Subject Devices in comparison to the Predicate Device.

List of Modifications ARTIS icono (floor, ceiling, biplane) / ARTIS pheno (VE50B)Systems
1. Updated system software from VE40A to VE50B to support the following:
A. Updated Peristepping / Perivision
B. New Postprocessing Algorithms (Advanced I-Noise and Extended Overlay Reference)
C. Updated ARTIS Touch UI
D. Updated Collimators
E. Updated Common Application Hosting

F. Updated User Interface
G. Updated ARTIS Profiles
2. Updated Imaging System PC Hardware
3. Updated Tilt Table
4. Updated system software from VD11D to VE50B which includes interface software component with Angio and CT systems known as Nexaris.
5. The ARTIS icono (Ceiling, Floor, and Biplane) / ARTIS pheno is also known as ARTIS icono.vision (Ceiling, Floor and Biplane) and ARTIS pheno.vision
6. Updated 510(k) information for the Primary Predicate Device

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 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 icono / ARTIS pheno (VE50B) systems are substantially equivalent to the legally marketed predicate listed in the table below:

Table 3: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
ARTIS icono (VE40A) (Floor, Ceiling & Biplane) ARTIS pheno (VE40A) Siemens	K241572	10/22/2025	• Indications for Use Statement • Updated system software from VE40A to VE50B • Peristepping/Perivision • I-Noise • ARTIS Touch UI • Collimator • Common Application Hosting • User Interface • ARTIS Profiles • Imaging System PC Hardware • Table
Artis zee/zeego & Artis Q/Q.zen Siemens	K181407	08/15/2018	• Nexaris

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

The ARTIS icono / ARTIS pheno (VE50B) 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 a floor configuration to provide specialized angiography systems. Components used with ARTIS configurations are either commercially available with current Siemens systems or include modifications to existing components. Technological differences between the Subject Devices and the Predicate Devices are provided in **Table 4** below for all modifications.

Table 4: Summary of Comparison of Technological Characteristics

Modifications	Subject Devices ARTIS icono (floor, ceiling, biplane) / ARTIS pheno (VE50B)	Predicate Device ARTIS icono and ARTIS pheno (VE40A) K241572	Comparison Results
New System Software/ Hardware Changes	1. Updated system software from VE40A to VE50B	System software version VE40A	**Comparable:** System software VE40 was updated to support modifications 1A-4. All Software modifications conform to "Guidance for the Content of Premarket Submissions for Device Software Functions". Provided in the software section of eSTAR is all required software testing per software guidance "Basic Level". Provided in the Non-Dicom Testing Section of eSTAR are Bench Test Summaries. Bench tests were conducted and were found acceptable and did not raise any new issues of safety or effectiveness. All software validation data demonstrates that the Subject devices are as safe and effective when compared to the Predicate Devices that are currently marketed for the same intended use. All test results met all acceptance criteria.
	A. Updated Peristepping / Perivision	Peristepping / Perivision available for ARTIS icono ceiling variant only	
	B. New Postprocessing Algorithms (Advanced I-Noise and Extended Overlay Reference)	iNoise	
	C. Updated ARTIS Touch UI	ARTIS Touch UI	
	D. Updated Collimators	Collimators	
	E. Updated Common Application Hosting	Third Party Interface (TPI)	
	F. Updated User Interface	User Interface	
	G. Updated ARTIS Profiles	ARTIS Profiles	
	2. Updated imaging system PC Hardware	Imaging system "ATIS"	
	3. Updated Tilt Table	Multi-Tilt Table	
	Proposed Device Modifications for the nexaris Angio-CT configuration		
	4. Updated system software from VD11D to VE50B which includes interface software component with Angio and CT systems known as Nexaris.	**Predicate Device** **Artis zee/zeego SW VD11D & Artis Q/Q.zen SW VD11DK181407**	
		Nexaris VD11D System Software (Angio and CT systems)	
	5. The ARTIS icono (Ceiling, Floor, and Biplane) / ARTIS pheno is also known as ARTIS icono.vision (Ceiling, Floor and Biplane) and ARTIS pheno.vision	**Trade Names**: ARTIS icono (ceiling); ARTIS icono (Floor); ARTIS icono (Biplane) and ARTIS pheno	
	6. Update 510(k) information for Predicate Devices		

9. Nonclinical Performance Testing:

During product development, non-clinical tests were conducted for The ARTIS icono / ARTIS pheno (VE50B) systems. The following non-clinical testing was conducted on the presented modifications: Updated Peristepping / Perivision testing includes peripheral imaging with and without subtraction. New Postprocessing Algorithms (Advanced I-Noise and Extended Overlay Reference) testing includes Real time image chain OGP parameters, Signal Noise, Strength Fluoro and Service parameter testing. Updated ARTIS Touch testing includes touch user interface mounting and functionality and hardware security. Updated collimator testing includes collimation centrically and collimation rectangular. Common Application Hosting testing includes External application interface and common applicating hosting configuration and layout testing. . Artis Profiles testing includes checks to verify available functionality to the clinical user. Software functional, verification, and System validation testing were conducted with passing results.

The ARTIS icono / ARTIS pheno (VE50B) systems were certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance and Electromagnetic Compatibility:

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
19-46	General II (ES/ EMC)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	ANSI AAMI
19-36	General II (ES/EMC)	Medical Electrical Equipment: Part 1: 1. Collateral Standard: Electromagnetic compatibility – Requirements and tests	60601-1-2:2020	IEC
12-336	Radiology	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	60601-1-3:2021	IEC
12-273	Radiology	Safety of laser products - Part 1: Equipment classification and Requirements	60825-1:2014 (recognized 2007)	IEC
5-137	General I (QS/RM)	Graphical symbols for electrical equipment in medical practice	TR 60878:2022	IEC
13-79	Software/ Informatics	Medical Device Software – Software Life Cycle Processes	62304:2015	IEC

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
12-309	Radiology	Medical electrical equipment - Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis	60601-2-28:2017	IEC
12-351	Radiology	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures	60601-2-43:2022	IEC
12-348	Radiology	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	60601-2-54:2022	IEC
2-258	Biocompatibility	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	10993-1:2018	ISO
5-125	General I (QS/RM)	Medical devices: Application of Risk management to medical devices	14971:2019	ISO
5-134	General I (QS/RM)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	15223-1:2021	ISO
14-579	Sterility	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.	17664-2:2021	ISO
6-483	General Plastic Surgery/ General Hospital	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	60601-2-35:2020	IEC
5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1:2020	IEC

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
12-341	Radiology	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	62563-1:2021	IEC
12-344	Radiology	Medical electrical equipment - Medical image display systems - Part 2: Acceptance and constancy tests for medical image displays	62563-2:2021	IEC
12-363	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1:2024e	NEMA
13-96	Software/ Informatics	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements	2900-1:2017	ANSI UL
13-104	Software/ Informatics	Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems	2900-2-1:2017	ANSI UL
13-83	Software/ Informatics	Principles for medical device security - Risk management.	TIR57:2016	AAMI
5-132	General I (QS/ RM)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	60601-1-6:2020	IEC
19-22	General II (ES/ EMC)	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.	TIR69:2017/ (R2020)	AAMI
19-48	General II (ES/ EMC)	American National Standard for Evaluation of Wireless Coexistence	USEMCSC C63.27-2021	IEEE ANSI
19-19	General II (ES/ EMC)	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	TR 60601-4-2:2016	IEC
5-135	General I (QS/ RM)	Medical devices - Information to be supplied by the manufacturer	20417:2021	ISO

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

Verification and Validation:
Software Documentation for a Basic level of concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for "Guidance for the Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with medical devices containing software. Non-clinical tests were conducted on the ARTIS icono / ARTIS pheno (VE50B) systems.

The Risk analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results show 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.

The ARTIS icono / ARTIS pheno (VE50B) systems were tested and found to be substantially equivalent for intended users, uses, and use environments through the design control verification and validation process. 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. The responsibility for compliance with IEC 80001-1-2010 is the hospital.

Summary:
Performance tests were conducted to evaluate the functionality of the ARTIS icono / ARTIS pheno (VE50B) systems. These tests have been performed to assess the functionality of the subject devices. The results of all conducted testing and clinical evaluation of images were found acceptable and did not raise any new issues of safety or effectiveness.

10. General Safety 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 / ARTIS pheno (VE50B) systems 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 are currently marketed for the same intended use.