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

April 16, 2020

Re: K193326
Trade/Device Name: ARTIS icono (VE2) System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, JAK, IZI
Dated: March 11, 2020
Received: March 12, 2020

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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)*
K193326

Device Name
ARTIS icono (VE2) 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 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 of 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 (VE2) K193326

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

Date Prepared: April 1, 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:**

   Ms. Patricia D. Jones
   Technical Specialist, Regulatory Submissions
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard, 65-1A
   Malvern, PA 19355
   Phone : (610) 448-6474
   Email : patricia.d.jones@siemens-Healthineers.com

3. **Device Name and Classification:**

Trade Name:	ARTIS icono (VE2) System
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 Predicate Device**

Trade Name:	ARTIS icono (VE2) System
510(k) Clearance	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, IZI, JAA, JAK
Total Product Life Cycle:	**There are no** product Recall incidents for this device.

5. Device Description:

Siemens is introducing a revolutionary new family of angiography systems, the ARTIS icono (VE2) a new modular angiography system designed to help healthcare professionals in today's stroke centers, deal with a double challenge: to treat more patients, and to treat them faster. This is literally expanding percision medicine to advance therapy outcomes.

The new ARTIS icono (VE2) system 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 physician can navigate catheters and other devices safely. The ARTIS icono (VE2) system 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 manipulate the catheters or other devices during x-ray. X-ray release is table side via a footswitch.

The ARTIS icono (VE2), 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 C-arm, stand, flat panel detector, x-ray tube, collimator, high voltage generator, patient table, and image post processing.

The ARTIS icono (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.

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 (VE2) system 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 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 (VE2) System is capable of 2D and 3D imaging. The c-arms can be mounted on the floor or for biplane systems on the floor and on 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 (VE2) screen configuration. Different screen configurations and layouts are possible in the examination room and in the control room.

The cleared "Predicate Device "ARTIS icono with software version VE2" supports the following product claims. These product claims are specific to cleared product features 510(k) cleared in the "Predicate Device".

Table 3: Product Claims

Claim #	Feature / Component	Labeling Claim
1	Improved Automatic Exposure Control (Structure Scout)	1a. Dose savings of 32-83% during fluoroscopy **at middle and high attenuations**, while maintaining the contrast to noise ratio of platinum **Disclaimer:** • The dose reductions were achieved with the CNR-driven exposure control comparing to the detector-driven exposure control. • They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 20-40 cm of patient equivalent thickness, here referred as middle and high attenuations. Contrast produced by a 0.01 mm thick platinum foil, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.
	Improved Automatic Exposure Control (Structure Scout)	1b. Dose savings of 52-86% during radiography at middle and high attenuations, while maintaining the contrast to noise ratio of platinum, **Disclaimer:**

Claim #	Feature / Component	Labeling Claim
		• The dose reductions were achieved with the CNR-driven exposure control comparing to the detector-driven exposure control. • They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 20-40 cm of patient equivalent thickness, here referred as middle and high attenuations. Contrast produced by a 0.01 mm thick platinum foil, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.
	Improved Automatic Exposure Control (Structure Scout)	1c. Dose savings of 78-81% during fluoroscopy and radiography at medium attenuation, while maintaining the contrast to noise ratio of tantalum* **Disclaimer:** • The dose reductions were achieved with the CNR-driven exposure control comparing to the detector-driven exposure control. • They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 20-30 cm of patient equivalent thickness, here referred as medium attenuations. Contrast produced by a 0.01 mm thick tantalum foil, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion.
	Improved Automatic Exposure Control (Structure Scout)	1d Dose savings of 3-27% during fluoroscopy, while maintaining the contrast to noise ratio of iron ***Disclaimer:** • The dose reductions were achieved with the CNR-driven exposure control comparing to the detector-driven exposure control. • They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 2.5-40 cm of patient equivalent thickness. Contrast produced by a 0.25 mm thick iron foil, located in the isocenter, and the surrounding noise were measured.

Claim #	Feature / Component	Labeling Claim
		• The contrast to noise ratio was calculated, considering the contrast- reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.
	Improved Automatic Exposure Control (Structure Scout)	1e. Dose savings of 22-52% during radiography at high attenuations, while maintaining the contrast to noise ratio of iodine **Disclaimer:** • The dose reductions were achieved with the CNR-driven exposure control comparing to the detector-driven exposure control. • They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 30-40 cm of patient equivalent thickness, here referred as high attenuations. Contrast produced by a 4 mm thick cavity, filled with iodine-based contrast material, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.
	Improved Automatic Exposure Control (Structure Scout)	1f. Dose savings of 27-44% during radiography at low attenuations, while maintaining the contrast to noise ratio of CO2 **Disclaimer:** • The dose reductions were achieved with the CNR-driven exposure control comparing to the detector-driven exposure control. • They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 2.5-20 cm of patient equivalent thickness, here referred as low attenuations. Contrast produced by a 4 mm thick CO2-filled cavity, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.

Claim #	Feature / Component	Labeling Claim
2	Improved Automatic Exposure Control	2a-1 Constant CNR independent of C-arm angulation and patient size – in support of ALARA dose. .**Disclaimer:** • The constant CNR is achieved within the physical limit of the x-ray tube. The dose reductions were achieved with the CNR-driven exposure control comparing to the detector dose-driven exposure control for the case when 80 nGy/frame yields clinically sufficient CNR at 25 cm patient equivalent thickness. They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 2.5-19 cm and 20-25 cm of patient equivalent thickness, here referred as low and medium attenuations, respectively. Contrast produced by a 0.25 mm thick iron foil, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.
		2a-2 Dose saving potential in fluoroscopy due to constant CNR of steel and nitinol devices is 55-79% for low attenuations and 10-49% for medium attenuations. **Disclaimer:** • The constant CNR is achieved within the physical limit of the x-ray tube. The dose reductions were achieved with the CNR-driven exposure control comparing to the detector dose-driven exposure control for the case when 80 nGy/frame yields clinically sufficient CNR at 25 cm patient equivalent thickness. They were obtained using a phantom composed of PMMA and aluminum plates to reproduce x-ray absorption and scattering in 2.5-19 cm and 20-25 cm of patient equivalent thickness, here referred as low and medium attenuations, respectively. Contrast produced by a 0.25 mm thick iron foil, located in the isocenter, and the surrounding noise were measured. • The contrast to noise ratio was calculated, considering the contrast-reducing (blurring) effects of the tube focus and object motion. Patient equivalent thickness refers to the physical thickness along the x-ray path excluding air cavities of a body having chemical element composition identical to the human body.
	Improved Automatic Exposure Control	2b Increased efficiency and time savings thanks to automatic adjustment of parameters. Full focus on procedure – system adapts to your choices of SID and collimation automatically

Claim #	Feature / Component	Labeling Claim
3	Improved Roadmap	3a Significant improvement of device contrast over vessel map, e.g. wires, markers and pipeline stents in Roadmap..
	Improved Roadmap	3d. Enhanced usability as Automap is integrated within the DSA Roadmap workflow.
	Improved Roadmap (DSA)	3f Mean dose savings of 28% in DSA at same contrast to noise ratio **Disclaimer:** The mean dose reduction was achieved using the new DSA protocol having 4 mask frames, comparing to the old protocol having 1 mask frame, both containing 19 fill frames on average. It was confirmed using a phantom composed of PMMA plates, reproducing x-ray absorption and scattering in 20 cm of patient thickness, and having a rotating tin foil insert simulating a vessel which is being filled with the contrast medium.
	Improved Roadmap	3g Increased device visualization by fading out the vessel map during fluoro break. With next fluoro vessel map will be superimposed again.
The below product claim for the ARTIS icono (VE2) was not submitted in the Pre-Submission Request		
4.	3D Imaging **syngo** DynaCT	With DynaCT interventionalists can visualize and assess intracranial bleedings in the angio lab.
5.	*syngo* DynaCT Sine Spin	With DynaCT Sine Spin interventionalists can visualize and assess intracranial bleedings in the angio lab.

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 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 (VE2) System is substantial equivalent to the legally marketed predicate device listed in the table below:

Table 4: Predicate Comparable Properties

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
ARTIS icono	K190768	09/12/2019	• Indications for use • Detector 3040CV • Software Version VD11D • Cabling Energy Chain • Floor Stand with Swivel base • CLEARstent Live • Artis basic table • AEC Dose regulation including structure scout • Gigalix tube • Antimicrobial coating • Collimator rotates in sealed housing • OR Tables • Ergonomic control modules • Megalix tube • Cabling Energy Chain

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

The ARTIS icono (VE2) System is designed as a set of components (C-arm, X-ray tube and housing, flat panel detector, digital imaging system, collimator, generator etc.) that may be combined into two different configurations (Floor & Biplane) to provide specialized angiography systems. Components used with ARTIS icono (VE2) System are either commercially available with current Siemens systems and cleared in “Predicate Device” 510(k) K190768. There are no technical differences in what was cleared in the “Predicate Device” 510(k). This submission addressed product claims only provided in the above table.

9. Nonclinical Performance Testing:

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

The ARTIS icono (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
- German national standard DIN 6868-157

Table 6: 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 9, 1999
9.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**.

FDA Guidance Document and Effective Date	
	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**

The product claims in this Premarket Notification are supported with a variety of supportive information for each product claim.

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 icono System software (VE2) during product development.

The Risk analysis was conducted, and risk controls were 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 icono 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. 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 icono (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 Device was cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that the ARTIS icono (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 Device that is currently marketed for the same intended use.