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

September 12, 2019

Re: K190768
Trade/Device Name: ARTIS icono (VE2)
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: August 9, 2019
Received: August 13, 2019

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)*

K190768

Device Name
ARTIS icono

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.

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary: ARTIS icono (VE2)

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

Date Prepared: March 22, 2019

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)
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 zee/zeego & Artis Q/Q.zen (Software VD11D)
510(k) Clearance	K181407
Clearance Date	August 15, 2018
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II

Product Code:	OWB
Subsequent Product Codes:	IZI, JAA, JAK
Total Product Life Cycle:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

Legally Marketed Secondary Predicate Device

Trade Name:	Artis one
510(k) Clearance	K133580
Clearance Date	April 28, 2014
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB,
Subsequent Product Codes:	IZI, 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.

Legally Marketed Secondary Predicate Device

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

Siemens is introducing a revolutionary new family of angiography sytems, 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 variaous 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 Subject device ARTIS icono with software version VE2 will support the following categories of modifications. These modifications were made to the Subject Device in comparison to the Predicate Devices:

1) **New/Modified Software & IFU:**

- **Table 1:** Overview of Software Modifications supported by software version VE2

Table 1. New Software Modifications for ARTIS icono (VE2) System

Software changes specific to New System Software VE2 (VE20)	
Device Software Modification & Applicable Configuration	
1	**Modified Indications For Use** Statement (*Floor & Biplane)*
2	**New System Software VE2** (also known as VE20), software modification/features.
3	**Improved Roadmap (Also known as OPTIQ)** (*Floor & Biplane)*
	A. Increased image quality dose ratio and faster workflow via new Architecture and Organ Program parametrization due to improved algorithms
	B. Improved Image Quality due to improved algorithim
	C. Subtracted fluoro mode: Dose, Time, and Contrast Agent Savings.
	D. Automap Integration in DSA Roadmap Workflow
4	**Improved Automatic Exposure Control:** (*Floor & Biplane)*
	A. New Automatic Exposure Control (AEC) incl. Structure Scout) B. CNR Driven Exposure Control (AEC)
5	**3D Imaging:** (*Floor & Biplane)*
	A. *syngo* Dyna3D HighSpeed
	B. *syngo* Dyna3D Sine Spin
	C. TwinSpin (3D with Frontal plane while lateral plane idle (no x-ray)
	D. *syngo* Dyna3D Multiphase
6	**Improved ClearStent Live: (***Floor & Biplane)*
7	**Updated User Interface:** (*Floor & Biplane)*
	A. Case Flow
	B. Favorites in control room and examination room
8	**Lateral Plane Switch (***Biplane)*
9	**Generic Interface for 3rd parties** for data transference (*Floor & Biplane)*

2) New/Modified Hardware:

- **Table 2:** Overview of Hardware Modifications supported by software Version VE2

Table 2. New Hardware Modifications

Device Hardware Modifications	
10	**New Multiaxis floor stand** (This hardware components enables the following features: High Speed, *syngo*Dyna3D & *syngo* DynaCT Sine Spin *(Floor & Biplane)*
11	**Agile lateral plane** *(Biplane)*
	A. Increased angulation (135->208)
	B. Improved repositioning precision
	C. Laser cross on Lateral Plane
	D. Cabling: energy chains in lateral plane
12	**Tables:** *(Floor & Biplane)*
	A. New Standard Table (Basic Table)
	B. New Siemens multi-tilt table (OR Table) (similar to secondary predicate ARTIS pheno)
13	**New Flat Detectors** *(Floor & Biplane)*
	A. Introduction of as21HDR Flat Detector aircooled (Trixell 2121CV)
	B. Introduction of as40HDR Flat Detector aircooled (Trixell 3040F)
14	**New Collimator** *(Floor & Biplane)*
	A. New Collimator (LFD) rotates within sealed housing (same as secondary predicate

	ARTIS pheno)
	B. New Collimator (MFD) rotates within sealed housing (same as secondary predicate Artis one)
15	**Universal Adapter for Megalix X-ray Tube** *(Floor & Biplane)*
16	**Anti-microbial Coating** *(Floor & Biplane)*
17	**New Control Modules** *(Floor & Biplane)*
18	**New Optional Touch Control Displays** *(Floor & Biplane)*
19	**New Variations of Display Ceiling Mounts** (*Floor & Biplane)*
	A. DCS-2x32'' rail mounted (in rails with stand)
	B. Large Display DCS with additional (Artis) display and ACUSON Freestyle display
	C. Optional rail (movable) mounted DCS on own rails for two 32" display
20	**New 3rd Party Accessory Heatable Mattress** *(Floor & Biplane)*
21	**Product Claims for the ARTIS icono (VE2)** *(Floor Biplane)*

3) List of Product Claims:

- **Table 3:** Product Claims

Table 3: Product Claims

Claim #	Feature / Component	Labeling Claim
1	Lateral Plane Switch	Preferred cardiology and neuroradiology lateral plane setup can be reached by an automated drive in less than 90 sec.
2	Lateral Plane Switch	Reduced scattered radiation dose to the user by positioning the tube opposite to the user
3	Lateral Plane Switch	The new biplane is engineered to accomodate two specialties (cardiology and neuroradiolgy) in one room instead of two rooms
4	Multi-axis floor stand	System supports the possibility to visualize anatomy with extreme CAUD angulations (up to 49°) with floor stand
5	Agile lateral plane	System supports the possibility to visualize anatomy with extreme CAUD angulations without mechanical limitations, except collision with the patient.
6	Reliability	Smart components increase uptime due to higher reliability. The Hepton multiaxis floorstand, the agile lateral plane and the table come with new smart Siemens industry motor gears and controllers. These components are significantly more reliable (compared to previous system) and can report their status via a remote service connection. 60% longer time between hardware component exchanges.
7	Multiaxis floor stand	Fully motorized stand positioning, no manual interaction necessary like in previous version (MULTISPACE.F).
8	Multiaxis floor stand	7% faster movement from head to left side/right side (13 sec from head to left side). Fully motorized stand positioning supports the workflow in sterile environment.
9	Multiaxis floor stand	Full Patient coverage of 2.10 m without repositioning the patient.
10	*syngo* Dyna3D High Speed	122% faster c-arm angulation for 3D, 100 degrees per sec instead of 45 degrees.* * Compared to Artis zee and Artis Q
11	Roadmap: increased image quality due to improved algorithms	Roadmap creation time reduced by 50%
12	Roadmap: increased image quality due to improved algorithms	Easy workflow with directly accessible Dynamic Progress via pilot module.

Claim #	Feature / Component	Labeling Claim
13	Roadmap: increased image quality due to improved algorithms	Fading out the vessel map during fluoro break by the touch of a button leads to visualization of the device.
14	Agile lateral plane	Full body coverage (210 cm versus previously 112 cm with frontal plane) with the lateral plane for 2D imaging.
15	Agile lateral plane	2D Imaging with the lateral plane during Prostate Artery Embolization and Uterine Fibroid Embolization procedures is possible with the biplane system.
16	*syngo* DynaCT multiphase	With *syngo* DynaCT Multiphase it is for the first time possible to assess the collateral status with time resolved DynaCT, depicting 8 different time points within a period of 50 seconds.
17	*syngo* DynaCT Sine Spin	*syngo* DynaCT Sine Spin helps interventionalists visualize bleedings in the interventional suite with a soft tissue resolution of 5 HU (@ 10 mm), respectively 10 HU (@ 5 mm), even in the basal part of the brain and close to the skull.
18	*syngo* DynaCT Sine Spin	*syngo* DynaCT Sine Spin is reducing cone beam CT artifacts in the basal part of the brain and close to the skull.
19	*syngo* DynaCT Sine Spin	Raising the bar in consistent 3D image quality for whole brain imaging from cranium to basal.
20	*syngo* DynaCT Sine Spin	In a stroke emergency setting the door-to-groin time can be shortened by up to 60 minutes by using *syngo* DynaCT and the angio only approach.
21	Favorites in Toolbars in control room	Image-type specific controls allow for 66% less clicks 1 click instead of 3 to get to the functionality you want Optimize/ Organize your workflow
22	Case Flow	Save 1 min, 64% shorter time (33 sec instead of 90 sec) during a Femoral Access Case Flow while keeping the focus on your patient.
23	Case Flow	Save 15 clicks (2 instead of 17) during a Femoral Access Case Flow while keeping the focus on your patient.
24	Case Flow	Case Flows allow reproducible system settings over labs and thereby can lead to standardization over labs.
25	Case Flow	With Case Flows the system can be positioned with zero joystick interaction using the pilot module.
26	Case Flow	Case Flows allow for standardized procedure execution with potential to reduce imaging variations.
27	Case Flow	Case Flows support new team members and rotating staff to get faster up to speed.
28	Shorter Control Module (Exam Room)	Shorter control modules/less buttons (19 % / 14 cm shorter), lead to more ergonomic system operation.
29	Shorter Control Module (Exam Room)	The control modules are within easier/shorter reach of the user.
30	Shorter Control Module (Exam Room)	14 cm shorter control modules better fit on lower radiation protection.
31	Shorter Control Module (Exam Room)	User stands 6 cm closer to the patient due to new table design. More ergonomic comfort leads to better working environment.
32	*syngo* DynaCT Sine Spin	Engineered for optimized stroke treatment
33	*syngo* DynaCT Sine Spin	Optimized DynaCT scan trajectory for an artefact reduced grey value resolution in the entire volume
34	Agile lateral plane	Engineered for better utilization between multiple / different modalities (combo use)
35	TwinSpin	Designed to seamlessly integrate 2D and 3D workflows
36	Lateral Plane Switch	Biplane system can switch via motorized movements between settings preferred in cardiology, radiology and neuroradiology.

Claim #	Feature / Component	Labeling Claim
		setup.

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 (primary) predicate listed in the table below:

Table 4: Predicate Comparable Properties

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate Artis Q/Q.zen (VD11)	K181407*	08/15/2018	• Indications for use • Detector 3040CV • Software Version VD11D • Cabling Energy Chain
Secondary Predicates Artis one	K133580	04/28/2014	• Floor Stand with Swivel base • CLEARstent Live • Artis basic table

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
ARTIS pheno	K163286	03/09/2017	• AEC Dose regulation including structure scout • Gigalix tube • Antimicrobial coating • Collimator rotates in sealed housing • OR Tables • Ergonomic control modules
Artis zee/zeego (VD11)	K181407*	08/15/2018	• Megalix tube • Detector 3040CV • Cabling Energy Chain
* K181407 was a bundled submission and applicable to both Artis Q/Q.zen (VD11) and Artis zee/zeego (VD11)			

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 or include modifications to existing components. Technological differences between the Subject Device and the Predicate Deivce is provided in the **Table 5** below for all modifications.

Table 5: Comparison of Technological Characteristics

Modification	Subject Device ARTIS icono (VE2)	Primary Predicate Device Artis Q/Q.zen (VD11D) K181407	Comparison Results
New System Software Changes 1-8	1. New System Software VE2 (also known as VE20), software modification/features	Software (VD11D)	**Modified:** This feature is modified from the Primary Predicate Device. All software changes are supported with System Validation testing is provided in **Appendix K Attachment 1-8**
	2. Improved Roadmap (Also known as OPTIQ) (*Floor & Biplane)*	Advanced Roadmap	**Modified:** This feature is modified from the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19** and System Validation testing is provided in **Appendix K Attachment 1-8**
	A. Increased image quality dose ratio and faster workflow via new Architecture and Organ Program parametrization due to improved algorithms		
	B. Improved Image Quality due to improved algorithim		
	C. Subtracted fluoro mode: Dose, Time, and Contrast Agent Savings.		
	D. Auto Map Integration in DSA Roadmap Workflow		

Modification	Subject Device ARTIS icono (VE2)	Primary Predicate Device Artis Q/Q.zen (VD11D) K181407	Comparison Results
	3. Improved Automatic Exposure Control: (*Floor & Biplane)*	**Secondary Predicate Device Atris pheno (K163286)**	**Same:** This feature remains unchanged from the Secondary Predicate Device and is only new for the Subject Device. All software changes are supported with Bench Testing. provided in **Section 19.** System Validation testing is provided in **Appendix K Attachment 1-8**
	A. New Automatic Exposure Control (AEC) incl. Structure Scout) B. CNR Driven Exposure Control (AEC)	Automatic Exposure Control	
	4. 3D Imaging: (*Biplane Floor)* A. syngoDyna3D HighSpeed	3D Imaging	**Same:** This feature remains unchanged from the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachments, 1-8**
	B. *syngo* DynaCT Sine Spin	*syngo* DynaCT	**Modified:** This feature is modified from the previously cleared syngo DynaCT in the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachment 1-8**
	C. TwinSpin (3D with Frontal plane while lateral plane idle (no x-ray)	*syngo* DynaCT	**Modified:** This feature is modified from the previously cleared *syngo* DynaCT in the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachments1-8**
	D. *syngo* DynaCT Multiphase	*syngo* DynaCT	**Modified:** This feature is modified from the previously cleared *syngo* DynaCT in the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K**

Modification	Subject Device ARTIS icono (VE2)	Primary Predicate Device Artis Q/Q.zen (VD11D) K181407	Comparison Results
			Attachments1-8
	5. Improved ClearStent Live: (*Floor & Biplane)*	ClearStent Live	**Modified:** This feature is modified from the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachments1-8**
	6. Updated User Interface: (*Floor & Biplane)* A. Case Flow B. Favorites in control room and examination room	User Interface	**Modified:** This feature is modified from the previously cleared Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachments1-8**
	7. Lateral Plane Switch (*Biplane)*	Lateral Plane	**Modified:** This feature is modified from the previously cleared Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachments1-8**
	8. Generic Interface for 3rd parties for data transference (*Floor & Biplane)*	User Interface	**Modified:** This feature is modified from the previously cleared feature in the Primary Predicate Device. All software changes are supported with Bench Testing provided in **Section 19.** System Validation testing is provided in **Appendix K Attachments1-8**

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 January 30, 2018
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
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**. 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 modifications described in this Premarket Notification were supported with verification and validation testing.

Verification and Validation:
Software Documentation for a Major Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on ARTIS icono System software (VE2) during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for 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 ot 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 devices were 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 Devices that is currently marketed for the same intended use.