October 22, 2024

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

Re: K241572
Trade/Device Name: ARTIS icono (VE40A) (floor); ARTIS icono (VE40A) (biplane); ARTIS icono (VE40A) (ceiling); ARTIS pheno (VE40A)
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: May 31, 2024
Received: May 31, 2024

Dear Patricia Jones:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241572

Device Name

ARTIS icono (VE40A) (floor);
ARTIS icono (VE40A) (biplane);
ARTIS icono (VE40A) (ceiling);
ARTIS pheno (VE40A)

Indications for Use *(Describe)*

ARTIS is a family of dedicated angiography systems developed for single plane and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the ARTIS family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities. This does not include projection radiography.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

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

The ARTIS systems include also the software option DynaCT with following indications for use:

DynaCT is an X-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary: ARTIS icono (VE40A) (floor)
ARTIS icono (VE40A) (biplane)
ARTIS icono (VE40A) (ceiling)
ARTIS pheno (VE40A)

510(k) Number: K241572

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

Date Prepared: October 22, 2024

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 Healthineers AG
   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 (VE40A) (floor)** **ARTIS icono (VE40A) (biplane)** **ARTIS icono (VE40A) (ceiling)** **ARTIS pheno (VE40A)**
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 (VE30A)**
510(k) Clearance	K230950
Clearance Date	December 14, 2023
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 Device

Trade Name:	**ARTIS icono (VE23) System**
510(k) Clearance	K221516
Clearance Date	July 19, 2022
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 Device

Trade Name:	**ARTIS pheno (VE30A)**
510(k) Clearance	K230949
Clearance Date	December 15, 2023
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:	JAA

Total Product Life Cycle: All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

5. Device Description:

The ARTIS Family (VE40A) 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 physicians can navigate catheters and other devices safely. The ARTIS Family (VE40A) consists of a patient table and a multi-axis motorized c-arm that can be positioned around the patient and angulated in a double-oblique fashion iso-centering the region of interest between the x-ray tube and the flat panel detector. The X-ray generator is placed separately. The displays for visualizing the X-ray images are mounted at the ceiling with a movable display suspension system. System operation is executed via control modules table side so that the physician can move and position the table and c-arm adequately for best imaging while manipulating catheters or other devices during the x-ray. X-ray release is tableside via a footswitch.

The ARTIS Family (VE40A) modular angiography systems are designed as sets of components that may be combined into four different configurations (Biplane, Floor, Ceiling, or the ARTIS pheno) to provide specialized angiography systems. In general, they are equipped with a C-arm, stand, flat panel detector, x-ray tube, collimator, high voltage generator, patient table, and image post-processing.

The ARTIS Family (VE40A) 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 Family (VE40A) system configurations, different display variants are used to visualize image and information content. Displays that visualize single images or large displays that are configurable to visualize multiple images and information contained in various layouts are used.

Post-processing can be done in the exam room or in the control room that offers monitors as well, with a footswitch location in the exam room or the control room. The ARTIS Family (VE40A) Systems are capable of 2D and 3D imaging. The c-arms can be mounted on the floor or for biplane systems on the floor, the ceiling or ARTIS pheno. Other systems and software *syngo* Application Software, *syngo* X Workplace, Sensis, and or third-party systems may also be integrated into the ARTIS Family (VE40A) screen configuration.

Different screen configurations and layouts are possible in the examination and control rooms.

The Subject device ARTIS Family (VE40A) supports the following modifications.

Software / Hardware changes specific to ARTIS Family (VE40A)
1. Updated system software from VE30A to VE40A (ARTIS icono floor & Biplane; & ARTIS pheno)
A. Added an optional Display
2. Updated system software from VE23 to VE40A (ARTIS icono ceiling)
A. Added feature "Xpand" (lateral movement of ceiling stand, ARTIS icono ceiling only)
3. Added an optional Display
4. Added new PC for imaging System due to obsolescence

6. Indications for Use:

ARTIS is a family of dedicated angiography systems developed for single-plane and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the ARTIS family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography, and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e., patient extremities. This does not include projection radiography.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

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

The ARTIS systems 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 Family (VE40A) of systems is 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
Primary Predicate Device: ARTIS icono (VE30A) (Floor & Biplane) Siemens	K230950	12/14/2023	• Indications for Use Statement • Updated system software from VE23 to VE40A • Added an optional Display
Secondary Predicate Device: ARTIS icono (VE23) (Ceiling Configuration) Siemens	K221516	07/19/2022	• Indications for Use Statement • Updated system software from VE23 to VE40A • Added feature "Xpand" (lateral movement of ceiling stand, ARTIS icono ceiling only) • Added optional Display • Added new PC
Secondary Predicate Device: ARTIS pheno (VE30A) Siemens	K230949	12/15/2023	• Added an optional Display

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

The ARTIS Family (VE40A) 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 four different configurations (Floor, Biplane, ceiling or the ARTIS pheno to provide specialized angiography systems. Components used with ARTIS configurations are either commercially available with current Siemens systems or included modifications to existing components. Technological differences between the Subject Device and the Predicate Device are provided in **Table 4** below for all modifications.

Table 4: Summary of Comparison of Technological Characteristics

Modifications	Subject Device ARTIS icono (VE40A) (floor) ARTIS icono (VE40A) (biplane) ARTIS icono (VE40A) (ceiling) ARTIS pheno (VE40A)	Primary Predicate Device ARTIS icono (VE30A) K230950 Secondary Predicate Device ARTIS pheno (VE30A) K230949	Comparison Results
New System Software/ Hardware Changes	1. Updated system software from VE30A to VE40A (ARTIS icono floor & Biplane; & ARTIS pheno)	System software version VE30A	**Comparable:** System software VE30 was updated to support modifications 1A & 2A, 3 & 4. All Software modifications conform to "Guidance for the Content of Premarket Submissions for Device Software Functions." Bench tests were conducted and found acceptable and did not raise any new safety or effectiveness issues. All software validation data demonstrates that the Subject device is as safe and effective as the Predicate Device currently marketed for the same intended use. All test results met all acceptance criteria.
	A. Added an optional Display	Displays	
	2. Updated system software from VE23 to VE40A (ARTIS icono ceiling)	**Secondary Predicate Device ARTIS icono (VE23) K221516**	
		System software version VE23A (Ceiling configuration)	
	A. Added feature "Xpand" (lateral movement of ceiling stand, ARTIS icono ceiling only)	Ceiling Longitudinal movement only	
	3. Added an optional Display	Displays	
	4. Added new PC for imaging System due to obsolescence	PC	

9. Nonclinical Performance Testing:

During product development, non-clinical tests were conducted for the ARTIS Family (VE40A). The following non-clinical testing was conducted on the presented modifications: XPAND - Ceiling Transversal Flow testing the steps the user performed to move the C-arm of the ARTIS icono ceiling system to several positions such as transfer positions, radial access position, typical cardiology projection. Software functional, verification, and System validation testing were conducted with passing results.

The ARTIS Family (VE40A) was 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
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	60601-2-43:2022	IEC

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
		essential performance of X-ray equipment for interventional procedures		
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
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
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1:2022	NEMA

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
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 documentation level 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" was conducted. The performance data demonstrates continued conformance with medical devices containing software. During product development, non-clinical tests were conducted on ARTIS Family System software (VE40A).

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.

ARTIS Family Systems software (VE40A) was 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 Family (VE40A) Systems. These tests have been performed to assess the functionality of the subject device. The results of all conducted testing were found acceptable and did not raise any new issues of safety or effectiveness.

10. General 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 devices were cleared based on non-clinical supportive information. Non-clinical test results demonstrate that the ARTIS Family (VE40A) 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 are currently marketed for the same intended use.