July 9, 2025

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

Re: K251520
Trade/Device Name: Cios Alpha; Cios Flow
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: May 16, 2025
Received: May 16, 2025

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.

510(k) Number *(if known)*
K251520

Device Name
Cios Alpha; CiosFlow

Indications for Use *(Describe)*
The Cios Alpha is a mobile X-Ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include, but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room procedures. The patient population may include pediatric patients.

The Cios Flow is a mobile X-Ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include, but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric patients.

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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K251520

510(k) Summary: Cios Alpha
Cios Flow

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

Date Prepared: May 16, 2025

1. **General Information:**
   Importer / Distributor:
   Siemens Medical Systems USA, Inc.
   40 Liberty Boulevard, 65
   Malvern, PA 19355
   Establishment Registration Number: 2240869

   Manufacturing Site:
   Roentgenstrasse 19 -21
   95478 Kemnath, Germany
   Establishment Registration Number: 3002466018

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:	**Cios Alpha**
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
Product Codes:	OWB
Subsequent Product Codes:	JAA, OXO

Trade Name:	**Cios Flow**
Classification Name:	Image-intensified fluoroscopic X-ray System
Common Name:	Interventional Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Regulatory Class:	Class II
Product Code:	OWB

Subsequent Product Codes: JAA, OXO

4. **Legally Marketed Primary Predicate Device**

Trade Name:	**Cios Alpha**
510(k) Clearance	K210055
Clearance Date	February 05, 2021
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
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO
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 applicable issues.

Trade Name:	**Cios Flow**
510(k) Clearance	K203504
Clearance Date	December 22, 2020
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
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO
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 applicable issues.

Secondary Predicate Device:

Trade Name:	**Cios Alpha**
510(k) Clearance:	K132094
Clearance Date:	March 11, 2014
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
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO
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.

Reference Devices

Trade Name:	**Ziehm Vision RFD**
510(k) Clearance:	K231692
Clearance Date:	November 20, 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
Product Code:	OWB
Subsequent Product Codes:	JAA,OXO

Trade Name:	**CIARTIC Move**
510(k) Clearance:	K233748
Clearance Date:	March 15, 2024
Classification Name:	Image-intensified fluoroscopic X-ray System
Common Name:	Interventional Fluoroscopic X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO

5. **Device Description:**

The Cios Alpha and Cios Flow (VA31A) mobile fluoroscopic C-arm X-ray System is designed for the surgical environment. The Cios Alpha and Cios Flow provide comprehensive image acquisition modes to support orthopedic and vascular procedures. The system consists of two major components:

a) The C-arm with X-ray source on one side and the flat panel detector on the opposite side. The C-arm can be angulated in both planes and lifted vertically, shifted to the side, and moved forward/backward by an operator.

b) The second unit is the image display station with a movable trolley for the image processing and storage system, image display, and documentation. Both units are connected with a cable.

The main unit is connected to the main power outlet, and the trolley is connected to a data network.

The following modifications were made to the predicate device Cios Alpha and Cios Flow. Siemens Medical Solutions USA, Inc. submits this Bundled Traditional 510(k) to request clearance for Subject Devices Cios Alpha and Cios Flow (VA31A) for the following device modifications made to the Predicates Device Cios Alpha and Cios Flow (VA30).

This 510(k) submission, Subject Devices "Cios Alpha" and "Cios Flow" with software version VA31A, will support the following categories of modifications made to the Subject Devices in comparison to the Predicate Devices:

Modified Software:

Table 1: Overview of Software/Hardware Modifications supported by Software Version VA31A

	Subject Devices Cios Alpha and Cios Flow (VA31A) Systems Modifications	Predicate Devices Cios Alpha (K210055) VA30 / Cios Alpha (K132094) VA10 Cios Flow (K203504) VA30
1.	Software updated from VA30 to VA31A to support the following software features:	VA30 System Software
	A. Updated InstantLink with Extended NXS Interface	InstantLink with NXS Interface
2.	Updated Collimator	Collimator
3.	New optional flat detector Trixell Pixium 3131SOD with IGZO (Indium Gallium Zinc Oxide) technology	**Cios Alpha (K132094) VA10**
		Flat detector: aSi detector in Secondary Predicate Cios Alpha VA10
4.	Updated FLC imaging system with new PC hardware	FLC imaging system PC
	Updated the High Performance Graphic Card on the Apphost PC	Apphost PC
5.	Updated Eaton UPS 5P 850i G2 as successor of UPS 5P 850i due to obsolescense	Eaton UPS 5P 850i
6.	The Cios Alpha is also known as "Cios Alpha.neo" The Cios Flow is also known as Cios Flow.neo	Trade name: Cios Alpha Trade name: Cios Flow

6. Indications for Use:

The **Cios Alpha** is a mobile X-ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include, but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room procedures. The patient population may include pediatric patients.

The **Cios Flow** is a mobile X-ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include, but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care, and emergency room procedures. The patient population may include pediatric patients.

Table 2: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate	K210055	02/05/2021	• Indications for Use • Software Version VA30 • Collimator • FLC Imaging PC • Apphost PC
Cios Alpha Siemens			

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
			• Eaton UPS
Cios Flow Siemens	K203504	12/22/2020	• Indications for Use • Software Version VA30 • Collimator • FLC Imaging PC • Apphost PC • Eaton UPS
Secondary Predicate Device Cios Alpha (VA10) Siemens	K132094	03/11/2014	• Flat Panel Detector (Amorphous Silicon)
Reference Devices Ziehm Vision RFD Ziehm	K231692	11/20/2023	• Flat Panel Detector (IGZO technology)
CIARTIC Move Siemens	K233748	03/15/2024	• Collimator

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

The Cios Alpha and Cios Flow (VA31A) Systems are substantially equivalent to the commercially available Siemens Cios Alpha (VA30), cleared with K210055 and Cios Flow (VA30) cleared with K203504. Indication for use remains unchanged. The technology and design of the Cios Alpha and Cios Flow are based on the predicate Cios Alpha and Cios Flow (VA30). Technological differences between the Subject Devices and the Predicate Devices are provided in **Table 3** below for all modifications.

Table 4: Summary of Comparison of Technological Characteristics

Modifications	Subject Devices Cios Alpha / Cios Flow (VA31A)	Predicate Devices Cios Alpha (K210055) VA30 / Cios Alpha (K132094) VA10 Cios Flow (K203504) VA30	Comparison Results
New System Software/ Hardware Changes	1. Software updated from VA30 to VA31A to support the following software features:	VA30 System Software	**Comparable:** System software VA31A was updated to support modifications 1A-5. Software modifications conform to "Guidance for the Content of Premarket Submissions for Device Software Functions". All software documentation meets "Basic Level" requirements. Bench tests were conducted and found acceptable and did not raise any new issues of safety or effectiveness. All software validation data demonstrate that the Subject devices are as safe and effective when compared to the Predicate Devices, that is currently marketed for the same intended use. All test results met all acceptance criteria.
	A. Updated InstantLink with Extended NXS Interface	InstantLink with NXS Interface	
	2. Updated Collimator	Collimator	
	3. New optional flat detector Trixell Pixium 3131SOD with IGZO (Indium Gallium Zinc Oxide) technology	**Cios Alpha (K132094) VA10**	
		Flat detector: aSi detector in Secondary Predicate Cios Alpha VA10	
	4. Updated FLC imaging system with new PC hardware	FLC imaging system PC	
	Added a High-Performance Graphic Card to the Apphost PC	Apphost PC	
	5. Updated Eaton UPS 5P 850i G2 as successor of UPS 5P 850i due to obsolescense	Eaton UPS 5P 850i	
	6. The Cios Alpha is also known as "Cios Alpha.neo". The Cios Flow is also known as "Cios Flow.neo".	Trade name: Cios Alpha Trade name: Cios Flow	The Cios Alpha and Cios Flow will also be known known as "Cios Alpha.neo" and "Cios Flow.neo"
The changes of the proposed modified device **Cios Alpha / Cios Flow (VA31A)** described in the table do not change the fundamental control mechanism, operating principle, energy type, or intended use found on predicate devices and supports substantially equivalents to the predicate devices **Cios Alpha (K210055) VA30 / Cios Alpha (K132094) VA10 and Cios Flow (K203504)** in accordance with its labeling.			

8. Nonclinical Performance Testing:

During product development, non-clinical tests were conducted for the Cios Alpha and Cios Flow (VA31A). The following non-clinical testing was conducted on the presented modifications: Updated software from VA30 to VA31A; updated InstantLink with NXS interface; updated collimator; optional flat panel detector; new PCs for imaging FLC and high-performance graphic card for Apphost; and an updated Eaton UPS power supply. Software functional, verification, and System validation testing were conducted with passing results.

The Cios Alpha and Cios Flow (VA31A) were certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance, and Electromagnetic Compatibility:
The modifications described in this Premarket Notification are supported by verification and validation testing.

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
19-49	General II (ES/ EMC)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section.	60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	IEC
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 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	IEC
12-336	Radiology	Medical Electrical Equipment: Part 1: 1. Collateral Standard: General requirements for radiation protection in diagnostic x-ray equipment	60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	IEC
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 Edition 3.2 2020-07 CONSOLIDATED VERSION	IEC
12-273	Radiology	Safety of laser products - Part 1: Equipment classification and	60825-1:2014	IEC

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
		Requirements	(recognized 2007)	
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 Edition 3.0 2017-06	IEC
12-351	Radiology	Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures	60601-2-43 Edition 3.0 2022-12	IEC
12-348	Radiology	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	60601-2-54 Edition 2.0 2022-09	IEC
5-125	General I (QS/RM)	Medical devices: Application of Risk management to medical devices	14971:2019	ISO
5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC
12-352	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20 2023e	NEMA
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 Edition 1.0 2016-05	IEC
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 Fourth edition 2021-07	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 First edition 2021-02	ISO
5-135	General I (QS/RM)	Medical devices - Information to be supplied by the manufacturer	20417 First edition 2021-04	ISO

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
			Corrected version 2021-12	
5-137	General I (QS/RM)	Graphical symbols for electrical equipment in medical practice [Including: Corrigendum 1 (2023)]	TR 60878 Ed. 4.0 2022-11	IEC
12-341	Radiology	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	62563-1 Edition 1.2 2021-07 CONSOLIDATED VERSION	IEC
12-344	Radiology	Medical electrical equipment - Medical image display systems - Part 2: Acceptance and constancy tests for medical image displays	62563-2 Edition 1.0 2021-11	IEC
13-38	Software/Informatics	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities	80001-1 Edition 1.0 2010-10	IEC
12-364	Radiology	Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy	61223-3-8 Edition 1.0 2024-03	IEC
13-83	Software/Informatics	Principles for medical device security - Risk management.	TIR57:2016	AAMI
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 First Edition 2017	UL ANSI
13-96	Software/Informatics	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements	2900-1 First Edition 2017	UL ANSI
13-131	Software/Informatics	Standard for medical device security - Security risk management for device manufacturers	SW96:2023	ANSI AAMI
19-48	General II (ES/EMC)	American National Standard for Evaluation of Wireless Coexistence	USEMCSC C63.27-2021	IEEE ANSI

Recog-nition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
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

Clinical Cadaver Report:
Summary of performed pre-market clinical development activities for Cios Flow VA31 and Cios Alpha VA31 new optional IGZO flat panel detector is as follows: In comparison to the a-Si detector, the IGZO detector can be regarded as non-inferior (equal or better) concerning the subjective image quality for four anatomical regions that have been investigated in the ortho-trauma setting.

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" is also included as part of this submission. The performance data demonstrates continued conformance with medical devices containing software. Non-clinical tests were conducted on Cios Alpha and Cios Flow software (VA31A) during product development.

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.

Cios Alpha and Cios Flow software (VA31A) were tested and found to be substantially equivalent for intended users, uses, and use environments through the design control verification and validation process. Customer employees are adequately trained in the use of this equipment.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse, or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 falls on the hospital. Cybersecurity information is provided in the Software Section, is the required cybersecurity information.

Summary:
Performance tests and a Clinical Evaluation were conducted to test the functionality of the Cios Alpha and Cios Flow software (VA31A) 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.

9. 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.

10. Conclusion as to Substantial Equivalence:

The predicate devices were cleared based on non-clinical supportive information. Non-clinical test results demonstrate that the Cios Alpha and Cios Flow software (VA31A) acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data, Clinical Cadaver Report, 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 and Indications for use.