Siemens Medical Systems USA, Inc.
Patricia Jones
Sr. Regulatory Affairs Technical Specialist
40 Liberty Boulevard, 65-1A
Malvern, Pennsylvania 19355

October 24, 2018

Re: K181560
Trade/Device Name: Cios Alpha
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO
Dated: June 12, 2018
Received: June 14, 2018

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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13002 26759, cn=Michael D. O'hara -S
Date: 2018.10.24 07:53:42 -04'00'

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K181560

Device Name
Cios Alpha

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: Cios Alpha

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Establishment Registration Number: 2240869

Date Prepared: October 2, 2018

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

Location of Manufacturing Site/Manufacturer:
SIEMENS AG Sector Healthcare
Röntgenstrasse 19 – 21
D-95478 Kemnath, Germany
Establishment Registration Number: 3002466018

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:	Cios Alpha
Classification Name:	Image-intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892. 1650
Device Class:	Class II
Product Code:	OWB, OXO

4. Legally Marketed Predicate Devices

Trade Name:	Cios Alpha
510(k) Clearance	K132094
Clearance Date	03/11/2014

Classification Name:	Image-intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, OXO
Recall Information:	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.
Trade Name:	ARTIS pheno
510(k) Clearance	K163286
Clearance Date	03/09/2017
Classification Name:	Image-intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number	21 CFR §892. 1650
Device Class:	Class II
Product Code:	OWB, JAA
Recall Information:	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.
Trade Name:	ARCADIS Avantic
510(k) Clearance	K051133
Clearance Date	03/09/2017
Classification Name:	Image-intensified Fluoroscopic X-Ray System
Regulation Number:	21 CFR §892. 1650
Device Class:	Class II
Product Code:	OWB, JAA
Recall Information:	No recalls

5. Device Description:

The Cios Alpha mobile fluoroscopic C-arm X-ray System is designed for the surgical environment. The Cios Alpha provides comprehensive image acquisition modes. The system consists of two major components:

a) The C-arm with an 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 component is the image display station with a moveable trolley that holds the image processing and storage system, and the image display. Both components are connected to each other with a cable.

The main C-arm component 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 the Cios Alpha. Siemens Medical Solutions USA, Inc. submits this Traditional 510(k) to request clearance for the Subject Device the Cios Alpha (VA30) for the following device modifications made to the Predicate Device (Cios Alpha (VA10).

The following software and hardware modifications are included in the Subject Device, Cios Alpha (VA30):

A new system software version (VA30) contains new software and hardware features for a new flat panel detector; new features Target Pointer, Cios Open Apps and Digital Cine Mode.

In addition to software changes this submission contains the following new hardware features: a remote control unit mounted on the cart; an anti-microbial coating on the C-arm and trolley, a wireless footswitch and a proposed claims list.

The modified Subject Device Cios Alpha is within the same classification regulation with the same indication for use as the predicate devices.

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.

7. Substantial Equivalence:

The Cios Alpha (VA30) is substantially equivalent to the commercially available primary predicate device Siemens Cios Alpha (VA10), cleared 11/03/2014 with K132094.

Indication for use remains unchanged the technology is similar. The predicate Flat Panel detector (a-Si technology) has been replaced by a CMOS Flat Panel detector. X-ray generation and control used with the Cios Alpha is similar to the technology used with the primary predicate device Cios Alpha. **Table 1** provides primary and secondary Predicate Device comparable information.

Table 1: Primary and Secondary Comparable Properties

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Siemens : Cios Alpha Product Codes: OWB, OXO	K132094	March 11, 2014	-Indications for Use

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate			-System for Image Acquisition - Post processing software -Detector
Siemens: ARTIS pheno Product Codes: OWB, JAA Secondary Predicate	K163286	March 09, 2017	-Anti-Microbial Coating -Anti-Microbial Coating Claims -Cleaning Instructions
Siemens : ARCADIS Avantic Product Codes: OXO Secondary Predicate	K051133	June 01, 2005	-Digital Cine Mode (DCM)
Reference 510(k) Information			
ZIEHM IMAGING GMBH **Reference 510(k):** ZIEHM Vision RFD **Product Codes:** OWB, OXO JAA	K132904	December 12, 2013	-Detector Information
ZIEHM IMAGING GMBH **Reference 510(k):** Solo FD Mobile Imaging System **Product Codes:** OWB, OXO JAA	K161976	October 6, 2016	-Detector Information

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

The Subject Device Cios Alpha (VA30) is substantially equivalent to the commercially available Siemens Cios Alpha (VA10), cleared 03/11/2014 with K132094 since the Indications for Use remains unchanged and technology and design of the Cios Alpha (VA30) is based on the Cios Alpha (VA10).

The predicate Flat Panel detector (a-Si technology) has been replaced by a CMOS Flat Panel detector and an optional available wireless footswitch is being introduced.

An anti-microbial coating is being added to the Cios Alpha (VA30) trolley. The anti-microbial coating and associated claims were cleared in the secondary Predicate Device the ARTIS pheno (K163286) on March 9, 2017.

A software function, Digital Cine Mode (DCM) the same function as the DCM Mode that was cleared in the secondary predicate device the ARCADIS Avantic (K051133) on June 1, 2005, was also added.

Table 2 below provides comparison of the Subject Device modification to the Predicate Devices.

Table 2: Comparison of Technological Characteristics

Subject Device Cios Alpha (VA30) Indications For Use Statement	Primary Predicate Device Cios Alpha (VA10) K132094 I ndications For Use Statement	Comparison Results
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 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.	Same

Property	Subject Device Cios Alpha (VA30)	Primary Predicate Device Cios Alpha (VA10) K132094	Secondary Predicate Device Artis Pheno K163286	Secondary Predicate Device ARCADIS Avantic K051133	Comparison Results
1. System Software	New Software Version VA30	Version VA10	N/A	N/A	VA30 was developed to support identified modifications (a-d). Testing requirements are acceptable per Software and SSXI guidance requirements.
	a) Two New Flat Panel Detectors New Detector XINEOS-3030HS and XINEOS 2222HS (Software & Hardware)	a-Si technology	CSX-30 Detector CMOS Technology	N/A	Equivalent image quality does not raise any new issues of safety of effectiveness. Non-clinical testing was conducted and is acceptable per SSXI Guidance Document
	b) Target Pointer (Software) This application enables the automatic detection of K-wires and displays the trajectory as a projection to the opposite edge of the image. Displaying the trajectory is intended to help the surgeon to better predict the position of the K-wire	N/A	N/A	N/A	Testing requirements are acceptable per Software Guidance, does not raise any new issues of safety of effectiveness.

Property	Subject Device Cios Alpha (VA30)	Primary Predicate Device Cios Alpha (VA10) K132094	Secondary Predicate Device Artis Pheno K163286	Secondary Predicate Device ARCADIS Avantic K051133	Comparison Results
	in an early phase of the insertion.				
	c) Cios Open Apps – (Hardware & Software)	N/A	N/A	N/A	Testing requirements are acceptable per Software Guidance, does not raise any new issues of safety of effectiveness.
	d) Digital Cine Mode (DCM) (Software)			Software function DCM mode	Same functionality as cleared in the secondary Predicate Device. Does not raise any new safety or effectiveness issues
2. Remote control Unit	Remote control unit available (unmodified); may be mounted on table or additionally on remote control unit cart	Remote control unit available; may be mounted on patient table	N/A	N/A	Does not raise any new safety or effectiveness issues
3. Additional of Optional Anti-Microbial Coating	Optional Anti-Microbial Coating (C-arm & Trolley) w/ cleaning instructions	N/A	Optional Anti-Microbial Coating (C-arm & Table Base)	N/A	Same Coating and Cleaning Instructions cleared in Artis pheno 510(k) K163286
4. Footswitch	Wired footswitch	Wired footswitch	N/A	N/A	Same
	Optional wireless footswitch	Wired footswitch	N/A	N/A	Optional wireless footswitch with same functionality like wired footswitch. Wireless version does not raise any new safety or effectiveness issues.
5. Product Claims List: Product claims list along with supportive information.					
6. Update 510(k) Predicate Information.					

The subject device modifications do not alter the fundamental scientific technology from the 510(k) cleared primary predicate device Siemens Cios Alpha (VA10), K132094 and secondary predicate devices Siemens ARTIS pheno K163286 and Siemens ARCADIS Avantic K051133.

9. Non-Clinical Performance Testing :

The Cios Alpha is certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following voluntary standards listed in **Table 3** below:

Table 3: Conformance Standards

Standards Development Organization Reference Number and Date	Standards Development Organization Reference Number and Date

Standards Development Organization Reference Number and Date		Standards Development Organization Reference Number and Date	
1	AAMI ANSI ES60601-1:2005/ (R)2012	7	IEC 60601-2-28:2010
2	AMI ANSI IEC 60601-1-2:2014	8	IEC 60601-2-43:2017 (recognized 2010)
3	IEC 60601-1-3:2013	9	IEC 60601-2-54:2009/A1:2015
4	IEC 60601-1-6:2010/A1:2013	10	ISO 14971:2007
5	IEC 60825-1:2014 (recognized: 2007)	11	IEC 62366-1:2015/Cor1:2016
6	IEC 62304:2015		

Table 4: FDA Guidance Documents

FDA Guidance Documents 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 (SSXI) 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: **Radio Frequency Wireless Technology**

FDA Guidance Documents and Effective Date	
	in Medical Device Document issued on August 14, 2007.
13.	Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices** Document issued on July 11, 2016

Verification and validation:
Software Documentation for a Moderate 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 the Subject Device Cios Alpha software version VA30 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.

The Cios Alpha software VA30 was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. All new software functions present in the Subject Device (Cios Open-Apps, Target Pointer, and Digital Cine Mode) have been validated through detailed software testing and it was founded they worked as intended. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

Siemens conforms to the cybersecurity **r**equirements 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.

Additional engineering bench testing was performed including: the non-clinical testing identified in the guidance for submission of 510(k) s for Solid State X-Ray Imaging Devices (SSXI); demonstration of system performance; and an imaging performance evaluation.

With regards to the flat panel detector (SSXI), the test documentation provided in this submission demonstrates compliance of the Cios Alpha to "Guidance for the

Submission of 510(k)'s for Solid State X-ray Imaging Devices". The evaluation includes but is not limited to the following performance specifications identified in the SSXI guidance, showing comparable or better performance of the Cios Alpha to its predicate and referenced devices. Provided in **Table 5** is comparative information showing the equivalence between the Subject and Predicate Device detectors.

Table 5: SSXI Specifications

SSXI Metrics	Cios Alpha Performance compared to Predicate and Reference Devices			
	Subject Device Cios Alpha (VA30)	**Predicate Device Cios Alpha (VA10) K132094**	**Reference Device Ziehm Vision RFD K132904**	**Reference Device Ziehm Solo FD K161976**
Imaging Modes	Pulsed fluoroscopy Single images	Pulsed fluoroscopy Single images	Pulsed Fluoroscopy Digital Spot	Pulsed Fluoroscopy Digital Spot
DQE	75% (small) 72% (large)	76%	Information Not Available	70%
Dynamic Range	96dB	94dB	Information Not Available	Equivalent
Modulation Transfer Function (MTF)	60% at 1 lp/mm (small) 58% at 1 lpmm large)	55% at 1 Lp/mm	Information Not Available	4lp/mm
Digitization depth	16 bit	16 bit	16 bit	16 bit
Pixel Pitch	152 µm	194µm	194 µm	100 µm
Field of View	Small FD: * 20 cm x 20 cm * 15 cm x 15 cm * 10 cm x 10 cm Large FD: * 30 cm x 30 cm * 20 cm x 20 cm	Small FD: * 20 cm x 20 cm * 15 cm x 15 cm * 10 cm x 10 cm Large FD: * 30 cm x 30 cm * 20 cm x 20 cm	FPD 20 cm: • 20 cm • 15 cm • 10 cm	FPD 20 cm: • 20 cm • 15 cm • 10 cm

Since Cios Alpha's´ new flat panel detector does not change the system's intended use and was found to be equivalent in technological characteristics, with the predicate device after conducting the test in the SSXI Guidance, clinical images are not required.

Summary:
Performance tests were conduct to test the functionality of the Cios Alpha (VA30). Results of all conducted testing 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 in the device labeling section. The labeling information provided will enable the user to operate the device in a safe and

effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Cios Alpha is continually monitored and if an error occurs, the system functions will be blocked and an error message will be displayed.

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 and mechanical 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 Cios Alpha (VA30) acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data and software validation demonstrates that the Subject Devices are as safe and effective when compared to the Predicate Devices that are currently marketed for the same intended use.