Siemens Medical Solutions USA, Inc.
% Mr. Cordell Fields, Esq.
Technical Specialists, Regulatory Submissions
40 Liberty Blvd., 65-1A
MALVERN PA 19355

February 5, 2021

Re: K210055
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, JAA
Dated: January 7, 2021
Received: January 8, 2021

Dear Mr. Fields:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210055

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

K210055

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

Date Prepared: January 07, 2021

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
   Roentgenstrasse 19 – 21
   95478 Kemnath, Germany
   Establishment Registration Number: 3002466018

2. **Contact Person:**
   Mr. Cordell Fields, Esq.
   Technical Specialist, Regulatory Submissions
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard, 65-1A
   Malvern, PA 19355
   Phone: (610) 306-3167
   Email: cordell.fields@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 Codes:	OWB, OXO
Subsequent Product Code:	JAA

4. **Legally Marketed Predicate Devices**

   Legally Marketed Primary Predicate Device

Trade Name:	Cios Alpha
510(k) Clearance	K181560

Clearance Date	October 24, 2018
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, OXO
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.

Legally Marketed Secondary Predicate Device

Trade Name:	Cios Flow
510(k) Clearance	K203504
Clearance Date	December 22, 2020
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, OXO
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 Cios Alpha (VA30) mobile fluoroscopic C-arm X-ray System is designed for the surgical environment. The Cios Alpha provides 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 be lifted vertically, shifted to the side and move forward/backward by an operator.

b) The second unit is the image display station with a moveable trolley for the image processing and storage system, image display and documentation. Both units are connected to each other 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. Siemens Medical Solutions USA, Inc. submits this Special 510(k) to request clearance for the Subject Device Cios Alpha (VA30) for the following device modifications made to the Predicate Device Cios Alpha (VA30).

This 510(k) submission, Subject Device "Cios Alpha" with software version VA30 will support the following categories of modifications made to the Subject Device in comparison to Predicate Devices:

Modified Software:

- **Table 1:** Overview of Software Modifications supported by Software Version VA30

Table 1: Software Modifications for Cios Alpha

Subject Device: Cios Alpha (VA30) Modifications/Features	
Software changes specific to New System Software VA30	
1.	Target Pointer
2.	Interactive User Touch Control **(Software component of VA30)**
	A. Collimation Controls
	B. Brightness Contrast Controls
	C. Rotate and Flip Controls
	D. Zoom and Pan Controls
	E. Spot Adapt
3.	Dose Regulation Indicator
4.	New Sound Radiation Delay
5.	New Product Software Security
Other Device Modifications	
6.	Update 510(k) Information

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) system is substantial equivalent to the legally marketed predicates listed in **Table 2** below:

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

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate Siemens' Cios Alpha	K181560	10/24/2018	• Indications for use • System for Image Acquisition • Post-processing Software • Examination Settings
Secondary Predicate Siemens' Cios Flow	K203504	12/22/2020	• Target Pointer • Interactive User Touch Control • Dose Regulation Indicator • Sound Radiation Delay • Product Software Security

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

The Cios Alpha (VA30) is substantially equivalent to the commercially available Siemens Cios Alpha (VA30), cleared with K181560.

Indication for use remains unchanged and technology and design of the Cios Alpha (VA30) is based on the predicate Cios Alpha (VA30).

Technological differences between the Subject Device and the Predicate Device is provided in **Table 3** below for all modifications.

Table 3: Summary of Comparison of Technological Characteristics

Comparison of Modifications to Predicate Devices			
	Subject Device Cios Alpha (VA30) Modifications	**Primary Predicate Device Cios Alpha K181560**	**Comparison Results**
1.	Target Pointer	**Secondary Predicate Device Cios Flow K203504 (The following modifications are derived from the secondary predicate device Cios Flow)** Target Pointer	**Same:** Target Pointer has the same functionality as cleared in the **Secondary Predicate Device Cios Flow K202504**. There are no technological differences in these features and the functionality of these features have not changed.
2.	Interactive User Touch Control **(Software components of VA30)**	Interactive User Touch Control	**Same: 2.A-E** has the same functionality as cleared in the Secondary Predicate device. The functionality of these features has not changed from the **Secondary Predicate device Cios Flow K203504.**
	A. Collimation Controls	Collimation Controls	
	B. Brightness Contrast Controls	Brightness Contrast Controls	
	C. Rotate and Flip Controls	Rotate and Flip Controls	
	D. Zoom and Pan Controls	Zoom and Pan Controls	
	E. Spot Adapt (Dose regulation with movable circle)	Spot Adapt (Dose regulation with movable circle)	
3.	New Dose Regulation Indicator	Dose Regulation Indicator	**Same:** The Dose regulation is equal to the **Secondary Predicate Cios Flow K203504**
4.	New Sound during Radiation Delay	Sound during Radiation Delay	**Same:** The Sound during Radiation Delay is equal to the **Secondary Predicate Cios Flow K203504**
5.	New Product Software Security	Product Software Security	**Same:** The updated Product Software Security functionality is the same as cleared in the **Secondary Predicate device Cios Flow K181560.**

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the Cios Alpha (VA30) during product development.

The Cios Alpha (VA30) 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 60825-1:2014
- IEC 62304:2015
- IEC 60601-2-28:2010
- IEC 60601-2-43:2010
- IEC 60601-2-54:2009/A1:2015
- ISO 14971:2019
- IEC 62366-1:2015/ Cor.1:2016

Table 4: FDA Guidance Documents

FDA Guidance Document and Effective Date	
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)** **Document issued on October 2, 2017**
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** **Document issued on September 13, 2019**
3.	Guidance for Industry and FDA Staff: **The Special 510(k) Program** **Document issued on September 13, 2019**
4.	Guidance for Industry and FDA Staff: **Deciding when to submit a 510(k) for a change to an existing device.** **Document issued on October 25, 2017**
5.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** **Document Issued on July 28, 2014**
6.	Guidance for Industry and FDA Staff: **Guidance for the Submission Of 510(k)'s for Solid State X-ray Imaging Devices** **Document issued on September 1, 2016**
7.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices** **Document issued on May 11, 2005**
8.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** **Document issued on September 27, 2019**
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**
14.	Guidance for Industry and FDA Staff: **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions** **Document issued on December 20, 2019**

The modifications described in this Premarket Notification are supported with verification and validation testing.

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 Cios Alpha (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. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer report and feedback form. Customer employees are adequately trained in the use of this equipment.

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

Summary:
Performance tests were conducted to test the functionality of Cios Alpha (VA30) 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 Cios Alpha (VA30) System acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data and software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.