December 22, 2020

Siemens Medical Solutions USA, Inc.
℅ Cordell Fields, Sr.
Regulatory Affairs Specialist
40 Liberty Boulevard 65-1A
MALVERN PA 19355

Re: K203504
Trade/Device Name: Cios Flow
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: November 25, 2020
Received: November 30, 2020

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. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement on last page.*

510(k) Number *(if known)* K203504

Device Name

Cios Flow

Indications for Use *(Describe)*

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.

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

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510(k) Summary: Cios Flow

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

Date Prepared: November 25, 2020

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

2. **Contact Person:**
   Mr. Cordell Fields
   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 Flow
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 Primary Predicate Device**

Trade Name:	Cios Fusion
510(k) Clearance	K153244
Clearance Date	March 07, 2016
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
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 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 Spin
510(k) Clearance	K181550
Clearance Date	October 30, 2018
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, 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 issue.

5. Device Description:

The Cios Flow (VA30) mobile fluoroscopic C-arm X-ray System is designed for the surgical environment. The Cios Flow 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 the Cios Fusion. Siemens Medical Solutions USA, Inc. submits this Special 510(k) to request clearance for the Subject Device Cios Flow (VA30) for the following device modifications made to the Predicate Device (Cios Fusion (VA20).

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

1) Modified Software:

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

2) Modified Hardware/Software:

- **Table 2:** Overview of Hardware Modifications supported by Software Version VA30

3) Modified Hardware changes

- **Table 3:** Overview of Hardware Modifications

Table 1. Software Modifications for Cios Flow

Software changes specific to New System Software VA30	
Device Software Modification	
1.	System Software VA30 software modifications/features
	A. Target Pointer
	B. Digital Cine Mode (DCM)
	C. Cios OpenApps
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
6.	Upgrade to Windows 10 Operating System

Table 2: Hardware/Software Modifications for Cios Flow

Software/Hardware changes specific to New System Software VA30	
Device Hardware/Software Modifications	
7.	System Software VA30 software/hardware modifications/features
	A. New CMOS Flat Panel Detector
	B. Wireless Foot Switch

Table 3. Hardware Modifications

Device Hardware Modifications	
8.	Optional Laser Light Localizer green
9.	Optional Cart for Remote Control Unit
10.	Anti-microbial Coating on C-Arm and Trolley
Other Device Modifications	
11.	Update 510(k) Information

6. Indications for Use:

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.

7. Substantial Equivalence:

The Cios Flow (VA30) system is substantial equivalent to the legally marketed predicates listed in **Table 3** 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 Siemens' Cios Fusion	K153244	03/07/2016	• Indications for use • System for Image Acquisition • Post-processing Software • Examination Settings • Cyber Security Information
Secondary Predicates Siemens' Cios Alpha	K181560	10/24/2018	• CMOS Flat Panel Detector - Large Detector: Xineos-30 cm x 30 cm - Small detector Xineos-20 cm x 20 cm • Wireless Foot Switch • Cart for Remote Control Unit • Anti-Microbial Coating • Target Pointer • Digital Cine Mode • Cios Open Apps • Windows 10
Secondary Predicates Siemens' Cios Spin	K181550	10/30/2018	• Laser Light Localizer green

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

The Cios Flow (VA30) System is designed as a set of components (floor stand, C-arm, X-ray tube and housing, flat panel detector, digital imaging system, collimator, generator etc.) that is combined to provide a mobile Interventional Fluoroscopic X-ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications.

Components used with Cios Flow (VA30) System are either commercially available with current Siemens systems or include updated modifications to existing components. Technological differences between the Subject Device and the Predicate Device is provided in **Table 4** below for all modifications.

Table 4: Summary of Comparison of Technological Characteristics

Comparison of Modifications to Predicate Devices			
	Subject Device Cios Flow (VA30 Modifications	**Primary Predicate Device Cios Fusion K153244**	**Comparison Results**
1.	System Software VA30 software modifications/features	**Secondary Predicate Device Cios Alpha K181560**	**Comparable: 1.A-C** have the same functionality as cleared in the **Secondary Predicate Device Cios Alpha K181560**. The functionality of Target Pointer has not changed except for better visualization of moving k-wires
	A. Target Pointer	Target Pointer	
	B. Digital Cine Mode (DCM)	Digital Cine Mode (DCM)	
	C. Cios OpenApps	Cios OpenApps	
2.	Interactive User Touch Control **(Software components of VA30)**	**Primary Predicate Device Cios Fusion K153244**	**Comparable: 2.A-E** has the same functionality as cleared in the Primary Predicate device, with exception to user interface is with Touch Control. The functionality of these features has not changed from the **Primary Predicate device Cios Fusion K153244.**
	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	Spot Adapt	
3.	New Dose Regulation Indicator	New Dose Regulation Indicator	**Comparable:** The Dose regulation is equal to the primary predicate Cios Fusion. While dose regulation remains the same, added is a visual feedback to the operator
4.	New Sound Radiation Delay	New Sound Radiation Delay	**Comparable:** Comparable to the primary predicate Cios Fusion typically there is a delay after press of button until the radiation starts. While the delay will be similar, there is now an acoustical feedback to the user that the button has been pressed, but radiation has not yet started.
5.	New Product Software Security	New Product Software Security	**Comparable:** This Product software provides additional cybersecurity feature to protect product security. The software functionality is the same except for inclusions of additional software security features. The updated functionality is the same as cleared in the **Primary Predicate device, Cios Fusion K153244.**
6.	Upgrade to Windows 10 Operating System	Upgrade to Windows 10 Operating System	**Same:** The Windows Operating System is the same as cleared in the Primary Predicate Device, with

Comparison of Modifications to Predicate Devices			
			exception to an upgraded version Windows 10. The upgraded functionality is the same as cleared in the **Primary Predicate device Cios Fusion K153244.**
7.	System Software VA30 software/hardware modifications/features	**Secondary Predicate Device Cios Alpha K181560**	**Same:** The CMOS Flat Panel Detector is the exact same detector cleared in the **Secondary Predicate Device Cios Alpha K181560.**
	A. CMOS Flat Panel Detector	CMOS Flat Panel Detector	
	B. Wireless Foot Switch	Wireless Foot Switch	**Same:** The Wireless Foot Switch is the same as in the **Secondary Predicate Device Cios Alpha K181560.**
8	Optional Laser Light Localizer, green	**Secondary Predicate Device Cios Spin K181550**	**Same:** The Optional Green Laser Light Localizer is the same aimer cleared in the **Secondary Predicate Device Cios Spin K181550**
		Optional Laser Light Localizer, green	
9	Optional Cart for Remote Control Unit	**Secondary Predicate Device Cios Alpha K181560**	**Same:** The Optional Cart for Remote Control Unit is the same cart cleared in the **Secondary Predicate Device Cios Alpha K181560.**
		Optional Cart for Remote Control Unit	
10	Anti-microbial Coating on C-Arm and Trolley	Anti-microbial Coating on C-Arm and Trolley	**Same:** The Anti-microbial Coating on C-Arm and Trolley is the same cart cleared in the **Secondary Predicate Device Cios Alpha K181560.**

9. Nonclinical Performance Testing:

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

The Cios Flow (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 60601-2-28:2017
- IEC 60601-2-43:2017
- IEC 60601-2-54:2009/A1:2015
- ISO 14971:2014
- IEC 62366-1:2015

Table 5: 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 Flow (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 Flow 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 Flow (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 Flow (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 Devices that is currently marketed for the same intended use.