July 29, 2025

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

Re: K251523
Trade/Device Name: Cios Spin
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: June 2, 2025
Received: June 2, 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,

for

Lu Jiang
Assistant Director
DHT8B: Division of Radiological 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)*
K251523

Device Name
Cios Spin

Indications for Use *(Describe)*

The Cios Spin 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: Cios Spin

510(k) Number: K251523

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

Date Prepared: July 28, 2025

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

   Manufacturing Site:
   Siemens Healthineers AG
   ROENTGENSTRASSE 19-21
   95478 KEMNATH, Germany
   Establishment Registration Number: 3002466018

2. **Contact Person:**
   Patricia D. Jones
   Regulatory Affairs Specialist
   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 Spin
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, JAA, OXO

4. **Legally Marketed Predicate Device**

Trade Name:	Cios Spin
510(k) Clearance	K210054
Clearance Date	February 5, 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.

Reference Device	
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 Spin (VA31A) mobile fluoroscopic C-arm X-ray System is designed for the surgical environment. The Cios Spin 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 following modifications were made to the Predicate Device the Cios Spin Mobile X-ray System cleared under Premarket Notification K210054 on February 5, 2021. Siemens Medical Solutions USA, Inc. submits this Traditional 510(k) to request clearance for the Subject Device Cios Spin (VA31A). The following modification is incorporated in the Predicate Device to create the Subject Device, for which Siemens is seeking 510(k) clearance:

Table 1: Subject Device Modifications

Subject Device Cios Spin (VA31A) System Modifications	
1.	Software updated from VA30 to VA31A to support the below software features
	A. Updated Retina 3D for optional enlarged 3D Volume of 25cm x 25cm x 16cm
	B. Introduction of NaviLink 3D Lite
	C. Universal Navigation Interface (UNI)
	D. Updated InstantLink with Extended NXS Interface

2.	Updated Collimator
3.	Updated FLC Imaging system PC with new PC hardware Updated AppHost PC with High Performance Graphic Card
4.	New Eaton UPS 5P 850i G2 as successor of UPS 5P 850i due to obsolescense

6. Indications for Use:

The Cios Spin is a mobile X-ray system designed to provide X-ray imaging of the anatomical structures of patients 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 Spin (VA31A) is within the same classification regulation with the same indications for use as the legally marketed predicate 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
Cios Spin (VA30) Siemens	K210054	02/05/2021	• Indications for Use Statement • Updated system software from VA30 to VA31A • Retina 3D image chain with 3D reconstruction mode 16 cm x 16 cm x 16cm • NaviLink 3D • Updated InstantLink with Extended NXS Interface • FLC imaging system PC • Apphost PC • Eaton UPS 5P 850i
Reference Device CIARTIC Move (VB10A) Siemens	K233748	03/15/2024	• Retina 3D for optional enlarged 3D volume 25cm x 25cm x 16cm • Universal Navigation Interface (UNI) • Collimator

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

The Indications for Use Statement is the same as the cleared Predicate Device “Cios Spin”. The Cios Spin with system software version VA31A contains the following modifications that were made to the predicate device. Provided in **Table 3** is a summary of the comparison of Technological Characteristics to the Predicate Device.

Table 3: Modification Comparison of Subject Device and Primary Predicate Device

Subject Device Cios Spin (VA31A) System Modifications		Predicate Device Cios Spin (VA30) K210054
1.	Software updated from VA30 to VA31A to support the below software features	VA30 System Software
	A. Updated Retina 3D for optional enlarged 3D Volume of 25cm x 25cm x 16cm	Retina 3D image chain with 3D reconstruction mode 16 cm x 16 cm x 16cm

	B. Introduction of NaviLink 3D Lite	NaviLink 3D
	C. Universal Navigation Interface (UNI)	n.a. (UNI in reference device CIARTIC Move)
	D. Updated InstantLink with Extended NXS Interface	InstantLink with NXS Interface
2.	Updated Collimator	Collimator
3.	Updated FLC Imaging system PC with new PC hardware Updated AppHost PC with High Performance Graphic Card	FLC imaging system and Apphost PC
4.	New Eaton UPS 5P 850i G2 as successor of UPS 5P 850i due to obsolescense	Eaton UPS 5P 850i
Comparison Results		
Modified: Updated System software from VA30 to VA31A, which includes the above software changes. All modification differences between the Subject Device and Predicate Device Software were tested in software VA31A. The System Software modifications listed in 1A-D conform to the "Guidance for the Content of Premarket Submission for Device Software Functions." The software feature "Enlarged Volume" was cleared in the CIARTIC Move (see Reference Device K233748). These software changes do not raise any new risks or issues regarding the safety or effectiveness of the device. All test results met all acceptance criteria.		

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the Cios Spin (VA31A) during product development. The Siemens Cios Spin (VA31A) has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed that the Siemens Cios Spin complies with the following 21 CFR Federal Performance Standards

Code of Federal Regulations Title 21 Subchapter J- Radiological Health, applicable sections include:

- 1020.30 Diagnostic X-Ray System and their major component
- 1020.32 Fluoroscopic Equipment

The Cios Spin (VA31A) was certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance, and Electromagnetic Compatibility:

- AAMI ANSI 60601-1-2:2014 [Including AMD 1:2021]
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
- IEC 60825-1:2014
- IEC 62304:2015
- IEC 60601-2-28:2017
- IEC 60601-2-43:2022
- IEC 60601-2-54:2022
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- ISO 14971:2019

- NEMA PS 3.1:2023e

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 5, 2022**
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** **Document issued on April 21, 2022**
3.	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**
4.	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**
5.	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**
6.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** **Document issued on August 11, 2023**
7.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Device Software Functions** **Document issued on June 14, 2023**
8.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**. **Document issued February 3, 2016**
9.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.** **Document issued on November 28, 2017**
10.	Guidance for Industry and FDA Staff: **Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions** **Document issued on September 27, 2023**
11.	Guidance for Industry and FDA Staff: **Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medical Devices** Document issued on September 14, 2018
12.	Guidance for Industry and FDA Staff: **Medical Device Accessories - Describing Accessories and Classification Pathways** **Document issued on December 20, 2017**
13.	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**
14.	Guidance for Industry and FDA Staff: **Electronic Submission Template for Medical Device 510(k) Submission** Document issued on October 2, 2023

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

Verification and Validation:
Software Documentation for a **Basic Documentation** Level software per FDA's Guidance Document "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 for medical devices containing software. A non-clinical test "Enlarged Volume Field of View" testing were conducted.

The Risk analysis was completed, and risk control was implemented to mitigate identified hazards. Testing supports 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.

Bench testing in the form of Unit, Subsystem, and System Integration testing was performed to evaluate the performance and functionality of the new software feature and software updates. All testable requirements in the Engineering Requirements Specifications keys, Subsystem Requirements Specifications keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process. The software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

Electrical safety and EMC testing were conducted on the Cios Spin, consisting of the acquisition unit (C-arm system) and the image processing and display station. The system complies with the IEC 60601-1, IEC 60601- 2-43, and IEC 60601-2-54 standards for safety and the IEC 60601-1-2 standard for EMC.

The Cios Spin with software (VA31A) 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 reports and feedback forms. Customer employees are adequately trained in the use of this equipment.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse, or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. The responsibility for compliance with IEC 80001-1-2010 is the hospital.

Summary:
Performance tests were conducted to test the functionality of the Cios Spin (VA31A). These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing and clinical assessments 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 and mechanical hazards, Siemens adheres to recognized and established industry practices, and all equipment is subject to final performance testing. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluation and post-processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information and data. Similar non-clinical test results demonstrate that the Cios Spin (VA31A) 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 Indications for use and intended use.