



November 4, 2025

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

Re: K250241

Trade/Device Name: Cios Select
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: September 30, 2025
Received: September 30, 2025

Dear Patricia D. 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,

A handwritten signature in black ink that reads "Lu Jiang". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

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

Indications for Use

510(k) Number (if known)

K250241

Device Name

Cios Select

Indications for Use (Describe)

The Cios Select is a mobile X-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care, and in Veterinary Medicine.

The Cios Select can operate in three different modes, Digital Radiography, Fluoroscopy, and Pulsed Fluoroscopy which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of an intra-medullary nail implants in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

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 Select

K250241

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

Date Prepared: January 22, 2025

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 Shanghai Medical Equipment Ltd.
278 Zhou Zhu Road, Shanghai
201318, China

Establishment Registration Number: 3003202425

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 Select
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, JAA

4. Legally Marketed Predicate Device

Trade Name:	Cios Select
510(k) Clearance	K223410
Clearance Date	December 7, 2022
Classification Name:	Image-intensified 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 products Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any applicable issues.

5. Device Description:

The Cios Select (VA21F) Mobile X-ray System is designed for the surgical environment. The Cios Select (VA21F) is a modification of the Cios Select (VA21) Flat Panel originally cleared under Premarket Notification K223410 on December 7, 2022.

The Cios Select consists of two major units:

The Siemens Healthineers Cios Select mobile fluoroscopy C-arm system is an X-ray imaging system consisting of two mobile units: a mobile acquisition unit and a monitor cart as the image display station.

The mobile acquisition unit is comprised of the X-ray control, the C-arm which supports the single-tank high-frequency generator/X-ray tube assembly, the flat panel detector, and user controls.

The monitor cart connects to the acquisition unit by a cable. It integrates the TFT flat panel displays, Digital Imaging Processing System, user controls and image storage devices (USB).

The following modifications were made to the predicate device the Cios Select (VA21) Flat Panel mobile X-ray System cleared under Premarket Notification K223410 on December 7, 2022. Siemens Medical Solutions USA, Inc. submits this Special 510(k) to request clearance for the Subject Device the Cios Select (VA21F) system in comparison to the Predicate Device.

1. Updated Software from VA21(E) to VA21(F) to support the following hardware changes.
 - a. Add one new Detector
 - b. Add one new Grid
2. Updated 510(k) Information

6. Indications for Use:

The Cios Select is a mobile X-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine.

The Cios Select can operate in three different modes, Digital Radiography, Fluoroscopy, and Pulsed Fluoroscopy which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of an intra-medullary nail implants in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

7. Substantial Equivalence:

The Cios Select (VA21F) system is substantial equivalent to the legally marketed predicates listed in **Table 1** below:

Table 1: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Predicate Device	K223410	12/7/2022	• Indications for use • X-ray technology • Image processing • Mechanical design • Cybersecurity • Software • Collimator • PC Hardware • Detector
Cios Select (VA21) Flat Panel Siemens.			

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

The Cios Select (VA21F) 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 specialized angiography system. Components used with Cios Select (VA21F) System are either commercially available with current Siemens systems or include modifications to existing components. Technological differences between the Subject Device and the Predicate Device is provided in the **Table 2** below for all modifications.

Table 2: Summary of Comparison of Technological Characteristics

Modifications	Subject Device Cios Select (VA21F)	Predicate Device Cios Select (VA21) Flat Panel K223410	Comparable Properties
1.Updated Cios Select system software from VA21(E) to VA21(F) to support the following hardware changes, with no new software features added.			
a. Detector	Detector PaxScan2121D X (11020805) Mercu0909F (11514190) K200218	Detector PaxScan2121DX (11020805)	The new detector has the same functionality as cleared in the Predicate Device Cios Select (VA21) Flat Panel K223410 and does not raise any new or effectiveness issue.
b. Grid	Grid	Grid	The new grid has the similar functionality as cleared in the Predicate Device Cios Select (VA21) Flat Panel K223410 and does not raise any new or effectiveness issue.

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the Cios Select (VA21F) with Flat Panel Detector during product development. The Siemens Cios Select (VA21F) with Flat Panel Detector has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed, that the Siemens Cios Select (VA21F) system 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 Systems and their major components

- 1020.32 Fluoroscopic Equipment
- 1040.10 Laser products

The Cios Select (VA 21F) system was certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance and Electromagnetic Compatibility:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- IEC 60601-1-2 Edition 4.1 2020-09 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 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC 60601-2-28 Edition 3.0 2017-06
- IEC 60601-2-43 Edition 3.0 2022-12
- IEC 60601-2-54 Edition 2.0 2022-09
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- ISO 14971:2019

Provided in **Table 3** is a list of relevant Guidance Documents that were used in the development of the 510(k) content.

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: Format for Traditional and Abbreviated 510(k)s 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 Off-The-Shelf Software Use in Medical Devices Document issued on September 27, 2019
8.	Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submission for Device Software Functions

	Document issued on June 14, 2023
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: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission Document issued on September 27, 2023
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
15.	Guidance for Industry and FDA Staff: Electronic Submission Template for Medical Device 510(k) Submission Document issued on October 2, 2023
16.	Guidance for Industry and FDA Staff: Electromagnetic Compatibility (EMC) of Medical Document issued on June 6, 2022
17.	Guidance for Industry and FDA Staff: Radio Frequency Wireless Technology in Medical Devices Document issued on August 14, 2007

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

Verification and Validation:

Software Documentation for a **Basic Documentation** Level of Concern 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 with special controls for medical devices containing software. Non-clinical tests were conducted on the Subject Device Cios Select VA21(F) 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.

Bench testing in the form of Unit, Subsystem and System Integration testing was performed to evaluate the performance and functionality of the new features, hardware, 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 has 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 Select, 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 Select VA21(F) 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. The required cybersecurity information is provided.

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 - X-ray Imaging Devices- Laboratory Image Quality and Dose Assessment, Tests and Standards was performed with acceptable results.

Summary:

Performance tests were conducted to test the functionality of the Cios Select (VA21F). 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 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 Cios Select (VA21F) has the same indications for use, operating environment, and mechanical design as the predicate. Siemens concludes via the documentation provided in the 510(k) submission that the Cios Select (VA21F) does not introduce any new potential safety risks and is substantially equivalent and performs as well as the predicate devices.