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

March 4, 2021

Re: K210307
Trade/Device Name: Cios Select (VA21) Image Intensifier
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 28, 2021
Received: February 3, 2021

Dear Cordell 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)*
K210307

Device Name
Cios Select (VA21) Image Intensifier

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 four different modes, Digital Radiography, Fluoroscopy, and Pulsed Fluoroscopy and Cassette exposure which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of a 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.

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510(k) Summary: Cios Select

K210307

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

Date Prepared: January 28, 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 Shanghai Medical Equipment Ltd.
   278 Zhou Zhu Road, Shanghai
   201318, China
   Establishment Registration Number: 3003202425

2. **Contact Person:**
   Cordell Field, 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 Select (VA21) Image-Intensifier**
Classification Name:	Image-Intensified Fluoroscopic X-Ray
Classification Panel:	System Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, OXO, JAA

4. **Legally Marketed Primary Predicate Device**

Trade Name:	**Cios Select**
510(k) Clearance	K153232
Clearance Date	February 10, 2016
Classification Name:	Image-Intensified Fluoroscopic X-Ray System, Mobile
Classification Panel:	Radiology

Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OXO, OWB, JAA
Total Product Life Cycle:	There are no Recalls nor MDR incidents for this cleared device.

Legally Marketed Secondary Predicate Device

Trade Name:	**Cios Select**
510(k) Clearance	K181767
Clearance Date	August 17, 2018
Classification Name:	Image-Intensified Fluoroscopic X-Ray System, Mobile
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OXO, OWB, 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:

This 510(k) submission, Cios Select (VA21) is a Mobile C-arm X-ray System. The Cios Select (VA21) is a modification of the Cios Select originally cleared under Premarket Notification K153232 on February 10, 2016.

The Cios Select consists of two major units:

One is the acquisition unit with the C-arm and movable base containing the generator, power unit, system control, and tube housing assembly on one side of the C-arm and the image intensifier on the opposite side.

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 Select Mobile X-ray System cleared under Premarket Notification K153232 on February 10, 2016. Siemens Medical Solutions USA, Inc. submits this Special 510(k) to request clearance for the Subject Device the Cios Select (VA21). The following minor modifications are incorporated in the Primary Predicate Device to create the Subject Device, for which Siemens is seeking 510(k) clearance:

The following modifications have been made to the Subject Device in comparison to the Predicate Device:

1) Upgraded software version to VA21
   A. Updated Image storage to a maximum of 300000 frames

B. Upgraded to Windows 10
C. Enhanced Cybersecurity
D. Optional WLAN for wireless transmission of DICOM Data

2) Optional Wireless Footswitch
3) New Image Intensifier

6. Indications for Use:

The Cios Select is a mobile x-ray system intended for use in Operation room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine. The Cios Select can operate in four different modes, Digital Radiography, Fluoroscopy and Pulsed Fluoroscopy and Cassette exposure which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of intra-medullary nail implant 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 (VA21) system is within the same classification regulation with the same indications for use as 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
Primary Predicate CIOS Select (VA10) w/Image Intensifer Siemens Shanghai Medical Equipment Ltd.	K153232	02/10/2016	• Indications for use • X-ray technology • Image processing • Mechanical design • Image Intensifier • Cybersecurity • Software
Predicate Device CIOS Select (VA20) w/Flat Panel Detector Siemens Shanghai Medical Equipment Ltd.	K181767	8/17/2018	• OTS Software Windows 10 • WLAN for Network • Wireless Footswitch

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

The Indications for Use Statement is exactly the same as the cleared Primary Predicate Device “Cios Select” VA10 (K153232).

The Cios Select with system software VA21 contains the following minor modifications that were made to the primary predicate device. Provided in **Table 2** is a summary of comparison of Technological Characteristics to Predicate Devices.

Table 2: Summary of Comparison of Technological Characteristics

	Subject Device Cios Select (VA 21) System Modifications	Primary Predicate Device Cios Select (VA10) K153232	Comparison Results
1.	Upgraded software to Version VA21	Software Version VA10	**Comparable:** System Software upgraded to VA21 to support new software and hardware modifications **1 A-C** which are comparable to the Primary Predicate Device. Software version VA21 supports additional image storage, Windows (OTS) software upgrade to Windows 10 and enhanced Cybersecurity. There are no new functionalities when compared to the **Primary Predicate Device Cios Select (VA10) K153232.** Tested per Software and OTS Software guidance requirements and does not raise any new safety or effectiveness issues.
	A. Updated Image storage to a maximum of 300000 frames	Image storage to a maximum of 150,000 frames	
	B. Upgraded to Windows 10	Windows 7 Software	
	C. Enhanced Cybersecurity	Cybersecurity	
	D. Optional WLAN for wireless transmission of DICOM Data	**Predicate Device Cios Select K181767**	**Same:** These features are the exact same features cleared in the **Secondary Predicate Device Cios Select (VA20) K181767** and does not raise any new safety or effectiveness issues.
		Optional WLAN for wireless transmission of DICOM Data	
2.	Optional Wireless Footswitch	Optional Wireless Footswitch	
3.	New Image intensifier	**Primary Predicate Device Cios Select (VA10) K153232**	**Comparable:** The new Image Intensifier does not raise any new safety or effectiveness issues. There are no new functionalities when compared to the **Primary Predicate Device Cios Select (VA10) K153232.**
		Image intensifier	

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the Cios Select (VA21) during product development. The Siemens Cios Select has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed, that the Siemens Cios Select complies with the following 21 CFR Federal Performance Standards

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

- 1020.30(c) Manufacturer's Responsibility (Certification)
- 1020.30(e) Identification of X-ray components
- 1020.30(g) Information to be provided to assemblers
- 1020.30(h) Information to be provided to users
- 1020.30(k) Leakage Radiation
- 1020.30(m) Beam Quality

- 1020.31(a) Peak Tube Potential
- 1020.32(a) Primary Protective Barrier Transmission
- 1020.32(b) Alignment of edges of the X-ray field with the edges of the fluoroscopic image receptor
- 1020.32(c) Activation of tube.
- 1020.32(d) Fluoroscopic Entrance exposure rate
- 1020.32(g) Source-skin distance
- 1020.32(j) Display of last-image-hold (LIH)
- 1020.32(k) Display of values of AKR and cumulative air kerma
- 1040.10 Laser products

The Cios Select (VA 21) 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
- TR 60878:2015
- IEC 62304:2015
- IEC 80001-1:2010
- IEC 60601-2-28:2017
- IEC 60601-2-43:2017
- IEC 60601-2-54:2009/A1:2015
- ISO 14971:2019
- IEC 62366-1:2015

Table 3: FDA Guidance Documents

FDA Guidance Documents and Effective Date	
1.	Guidance for Industry and Food and Drug Administration 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 Food and Drug Administration Staff: **The Special 510(k) Program – Guidance for Industry and FDA Staff.** Document issued on September 13, 2019
4.	Guidance for Industry and Food and Drug Administration 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

FDA Guidance Documents and Effective Date	
6.	Guidance for Industry and Food and Drug Administration Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices.** Document issued on May 11, 2005
7.	Guidance for Industry and Food and Drug Administration Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices.** Document issued on September 9, 1999
8.	Guidance for Industry and Food and Drug Administration Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.** Document issued on November 28, 2017
9.	Guidance for Industry and Food and Drug Administration Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical devices.** Document issued on October 2, 2014
10.	Guidance for Industry and Food and Drug Administration Staff: **Radio Frequency Wireless Technology in Medical Device.** Document issued on August 14, 2007.
11.	Guidance for Industry and Food and Drug Administration Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices.** Document issued on July 11, 2016

The modifications described in this Premarket Notification are supported with Bench test Summaries and System 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 the Subject Device Cios Select software version VA21 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 software (VA21) was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. 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. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section, is the required cybersecurity information.

Summary:
Performance tests were conducted to test the functionality of Cios Select (VA21) System. These tests have been performed to assess the functionality of the subject device. 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 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 Select (VA21) 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.