August 17, 2018

Siemens Medical Solutions USA, Inc.
% Ms. Patricia Jones
Senior Regulatory Affairs Technical Specialist
40 Liberty Boulevard, 65-1A
MALVERN PA 19355

Re: K181767
Trade/Device Name: Cios Select
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO
Dated: July 02, 2018
Received: July 03, 2018

Dear Ms. 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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 below.

510(k) Number *(if known)*

K181767

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 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.

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

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Section 7
510(k) Summary

The 510(k) Summary is provided on the next page and is suitable for publication on the FDA website.

510(k) Summary: Cios Select

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

Date Prepared: August 16, 2018

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:
2. 2240869

Manufacturing Site:
Siemens Shanghai Medical Equipment Ltd.
278 Zhou Zhu Road, Shanghai
201318, China
Establishment Registration Number:
3003202425

2. Contact Person:
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Phone: (610) 448-6474
Email: patricia.d.jones@siemens-Healthineers.com

3. Device Name and Classification:

Trade Name:	Cios Select
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Submission Type:	Traditional 510(k)
Device Class:	Class II
Product Code:	OWB
Subsequent Product Code:	OXO

4. **Legally Marketed Predicate Device:**

Primary Predicate:

Trade Name:	Cios Select
510(k) #:	K153232
Clearance Date:	February 10, 2016
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Code:	JAA, OXO
Recall Information:	No Recalls

Secondary Predicate:

Trade Name:	Cios Fusion
510(k) #:	K153244
Clearance Date:	March 07, 2016
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Code:	OXO
Recall Information:	No Recalls

5. **Device Description:**

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 (DVD, USB).

The new detector PaxScan 2121DXV is a new component to the subject device Cios Select. This is a hardware change that impacts the system software VA20. The essential performance of the detector is to generate (a sequence of) digital images in which the digital pixel values are representative of the intensity of the spatially distributed X-Ray radiation at the position of the detector. All the non-clinical performance data demonstrate that the detector PaxScan 2121DXV for Cios Select VA20 does not raise any new issues of safety or effectiveness and is as safe, and effective when compared to the secondary predicate devices Cios Fusion (K153244) that is currently marketed for the detector technology.

Interfaces are provided for optional devices such as external monitors, thermal printers, as well as wired and wireless DICOM network interfaces.

The following modifications are incorporated to create the Subject Device the Cios Select (VA20):

1. Updated the Indications for Use Statement with minor changes
2. Upgraded software, from Version VA10 to Version VA20:
   a. New User Interface touch panel **– (*software*)**
   b. New flat detector (PaxScan 2121DXV) ***(software)***
   c. (OTS) software from Windows 7 to Windows 10. (***software)***
   d. Updated Image storage to a maximum of 300000 frames ***(software)***
   e. Optional Metal Artifact Reduction Software (cleared in Secondary Predicate Cios Fusion K153244)

3. New user interface in-touch panel for navigating and operating the system. (***Hardware)***
4. New optional wireless LAN for network connectivity (***Hardware)***
5. New optional wireless footswitch in addition to the wired footswitch. ***(Hardware)***
6. New flat detector (PaxScan 2121DXV) to replace image intensifier for image receptor.(***Hardware)***

6. **Indication 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 (VA20) is substantially equivalent to the commercially available primary predicate device Siemens Cios Select (VA10), cleared February 10, 2016, with K153232.

   The Indications for Use was slightly modified, however, the change does not impact the Intended Use of the device. **Table 1** provides primary and secondary Predicate Devices comparable information:

The Cios Select is substantially equivalent to the following predicate devices:

Table 1: Predicate Device Comparable Properties:

Predicate Device(s) Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate Device Cios Select (VA10) **Product Code:** OWB, OXO, JAA Siemens Shanghai Medical Equipment Ltd.	K153232	2/10/2016	• ndications for use • -ray technology • mage processing • echanical design
Secondary Predicate Device Cios Fusion (VA20) **Product Code:** OWB, OXO Siemens Healthcare GmbH	K153244	3/07/2016	• etector Technology

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
   The Subject device Cios Select design is based on the Siemens Cios Select(K153232) including the system control, mechanical design and image processing functions. The flat panel detector technology is based on the Cios Fusion (K153244).

   The subject device has the same fundamental scientific technologies as the
   predicate devices. The modifications do not affect the intended use of the device. **Table 2** has Subject Device characteristics compared to the Predicate Device.

Table 2: Comparison of Technological Characteristics

Modifications	Subject Device Cios Select (VA20)	Primary Predicate Device Cios Select (VA10) K153232	Secondary Predicate Device Cios Fusion (VA20) K153244	Comparison Results
System Software	Upgraded software, from Version VA10 to Version VA20.	Software Version VA10	N/A	System Software upgraded to VA20 to support new software / hardware modifications and tested per software and guidance and SSXI Guidance. All test results passed.
User Interface	New user interface in a touch panel for navigating and operating the	Keyboard button based User interface	N/A	The functionality of the device remains the same as the predicate device except for the new User Interface with

Modifications	Subject Device Cios Select (VA20)	Primary Predicate Device Cios Select (VA10) K153232	Secondary Predicate Device Cios Fusion (VA20) K153244	Comparison Results
	system.			Touchscreen panel.
WLAN	New optional wireless LAN for network connectivity.	N/A	N/A	The WLAN network connectivity feature is in compliance with the Wireless Guidance document.
Footswitch	Wired Optional Wireless footswitch	Wired Only	N/A	Optional wireless footswitch with the same functionality as a wired footswitch. Wireless version does not raise any new safety or effectiveness issue. This feature is in compliance with the Wireless Guidance document.
Image Receptor	New flat detector PaxScan (2121DXV)	Image Intensifier	Detector PaxScan™ 2020X and PaxScan™ 3030X Detector was cleared in the predicate	Detector technology is comparable to secondary predicate device Cios Fusion (K153244) per the SSXI Guidance document and does not raise any new safety or effectiveness issues.
Off The Shelf Software	Upgraded Off-the-Shelf (OTS) software from Windows version 10.	Windows 7	N/A	Tested per Software Guidance and Off the Shelf Software Guidance.
Image Storage	Updated Image storage to a maximum of 300000 frames.	150000 frames	N/A	Increased system capability for image storage. This modification does not raise new issues of safety or effectiveness.

9. Non-Clinical Testing

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:

1020.30 Diagnostic X-Ray Systems and their major components
1020.32 Fluoroscopic equipment
1040.10 Laser products

and with the following relevant voluntary FDA Recognized Consensus Standards as listed in the table below:

Table 3: Voluntary Conformance Standards:

Recog-nition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
19-4	General	Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005	60601-1:2012, ed. 3.1	IEC
19-8	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2 Edition 4.0 2014-02	IEC
12-269	Radiology	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	60601-1-3 Edition 2.1 2013-04	IEC
5-114	General	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	62366-1 Edition 1.0 2015-02	IEC
5-70	General I (QS/RM)	Medical devices – application of risk management to medical devices	14971:2012	ISO
13-32	Software	Medical device software - Software life cycle processes	62304 Ed. 1.0 2006	IEC
12-204	Radiology	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	60601-2-28 Edition 2.0 2010-03	IEC
12-202	Radiology	Medical electrical equipment- Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	60601-2-43 2010	IEC
12-274	Radiology	Medical electrical equipment - Part 2-	60601-2-54:	IEC

Recog-nition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
		54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	2009	
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20 (2011)	NEMA
12-273	Radiology	Safety of laser products – Part 1: Equipment classification, and requirements	60825-1 Edition 2.0 2007-03	IEC
12-290	Radiology	Medical electrical equipment - Radiation dose documentation - Part 1: Equipment for radiography and radioscopy	61910-1 Edition 1.0 2014-09	IEC

Table 4: FDA Guidance Documents

FDA Guidance Documents 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 January 30, 2018
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
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 9, 1999
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**

FDA Guidance Documents and Effective Date	
	Management of Cybersecurity in Medical devices. Document issued on October 2, 2014
12.	Guidance for Industry and FDA Staff: **Radio Frequency Wireless Technology in Medical Device** Document issued on August 14, 2007.
13.	Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices** Document issued on July 11, 2016

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 VA20 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 were 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 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 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 the standard for EMC.

The Cios Select software (VA20) was tested and found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. All new software functions present in the Subject Device (New User Interface touch panel, New flat detector (PaxScan 2121DXV), (OTS) software from Windows 7 to Windows 10 and Updated Image storage to a maximum of 300000 frames) have been validated through detailed software testing and it was

founded they worked as intended. 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. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section, is the required cybersecurity information.

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 (VA20). 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 has the same indications for use, operating environment, and mechanical design as the Primary and Secondary predicates. Siemens concludes via the documentation provided in this 510(k) submission that the Cios Select does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as the

predicate devices even though the Subject Device is using a different detector.