DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2016

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

Re: K153232
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, JAA
Dated: January 18, 2016
Received: January 19, 2016

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153232

Device Name

Cios Select

Indications for Use *(Describe)*

The Cios Select is a mobile x-ray system intended for use in Operation room, Traumatology, Endoscopy, Intensive Care Station, Paediatrics, 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.

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

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

Date Prepared: February 9, 2016

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:

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
Fax: (610) 640-4481
Email: patricia.d.jones@siemens.com

3. Device Name and Classification:

Trade Name:	Cios Select
Classification Name:	Image-Intensified Fluoroscopic X-Ray System, Mobile
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650

Submission Type:	Special
Device Class:	Class II
Product Codes:	OXO, OWB
Secondary Product Code:	JAA

4. Legally Marketed Predicate Device

Trade Name:	Siremobil Compact
510(k) #:	K963093
Clearance Date:	September 3, 1996
Classification Name:	Image-Intensified Fluoroscopic X-Ray System, Mobile
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OXO
Recall Information:	1 Recall **(**See **Appendix H)**

5. Device Description:

This 510(k) submission, Cios Select is a Mobile Fluoroscopic C-arm X-ray System. The Cios Select is a modification of the Siremobil Compact originally cleared under Premarket Notification K963093 on September 3rd, 1996.

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 Siremobil Compact Mobile X-ray System cleared under Premarket Notification K963093 on September 03, 1996. Siemens Medical Solutions USA, Inc. submits this Special 510(k) to request clearance for the Subject Device the Cios Select. The following minor modifications are incorporated to create the Subject Device and have not received prior 510(k) clearance for the Subject Device:

1. Upgraded software platform from Memoskop to Fluorospot Compact (SW VA10) ***Modification Affects: Hardware & Software***

2. Fluorospot Compact SW VA10 contains the following software functional changes:
   - New user interface in navigating and operating the system in terms of interactive elements on screen and on control keyboard.
     Modification Affects: Hardware, Software & Labeling
3. A new single tank with a new integrated X-ray tube and a new generator. ***Modification Affects: Hardware & Software***
4. Updated Image storage to maximum of 150000 frames
   Modification Affects: Hardware & Software
5. New optional detachable grid.
   Modification Affects: Hardware & Software
6. Upgraded Off-the-Shelf (OTS) software from Windows XP to Windows 7. ***Modification Affects: Software***
7. Optional upgrade of external monitor connectivity from VGA to DVI port. ***Modification Affects: Hardware***
8. Added integrated power supply (UPS)
   Modification Affects: Hardware
9. Product Claims List (See **Appendix F**)
10. Provided Update 510(k) Information (See **Appendix G**)

The modified Subject Device is within the same classification regulation with the same indication for use as the predicate device (Siremobil Compact**).**

Provided in **Section 14** of this 510(k) submission, is a completed "510(k) Decision Making FlowChart". We believe these modifications are eligible for the Special 510(k) process since the Subject Device has the same fundamental scientific technology, Intended Use and Indications for Use as the predicate device system. Documentation is provided to support a claim of substantial equivalence to Siemens' predicate device the Siremobil Compact K963093.

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 Subject Device (Cios Select) is within the same classification regulation with the same indication for use as the predicate device Siremobil Compact (K963093 on September 3, 1996) (see **Table 1**). Documentation is provided to support a claim of substantial equivalence to the Siemens' predicated device.

Table 1: Predicate Device Comparable Properties to Subject Device

Predicate Device(s) Name and Manufacturer: Siemens AG	**510(k) Number**	**Clearance Date**	**Comparable Properties**
Predicate Device : Siremobil Compact **Product Code**: OXO	K963093	09/03/1996	Indication for use X-ray technology Image processing Mechanical design

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

The Cios Select with system software VA10 version contains the following minor modifications that were made to the predicate device: a different software platform software, new user interface features, several components contained within a single tank (new x-ray tube, new x-ray generator, and a collimator), an increase in storage space by 150,000 frames, an optional detachable grid, update OTS software from Windows XP to Windows 7, an optional upgrade of external monitor connectivity from VGA to DVI port and added an integrated power supply (UPS).

Explanation of these minor modifications is supported in the submission with non-clinical testing. These minor modifications difference between the new device and the predicate device do not raise different questions of safety and effectiveness.

The Subject Device has the same comparable properties (see **Table 1** Comparable properties) as the predicate device.

9. Non-Clinical Testing:

Non-clinical tests were conducted for the Cios during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. Siemens claims conformance to the following performance standards: 60601-1:2012, ed. 3.1, 60601-1-2 3rd 2007; 60601-1-3: 2008+A1:2013; 62366: 2007; 14971:2010; 62304 Ed. 1.0 2006; 60601-2-28 Edition 2.0 2010-03; 60601-2-43:2010; 60601-2-54 2009; PS 3.1 - 3.20 (2011) and 60825-1:2007.

Electrical safety and Electromagnetic Compatibility (EMC) testing were conducted on the Subject Device to comply with the IEC 60601-1 3rd, and the IEC 60601-1-2 3rd standard for EMC. All tests passed.

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 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports 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.

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. Contained in **Attachment 7** of this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 8001-1-2010 is the hospital. Provided in the Software section, (**Section 18**) and the Operator's Manual (**Appendix B**) is the required cybersecurity information.

Summary:
Performance tests were conducted to test the functionality of the Subject Device system. These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

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 predicate device was cleared based on non-clinical supportive information. The results of these tests also demonstrate that the Cios Select acceptance criteria are adequate for this intended use. The comparison of technological characteristic, 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 intended use and indication for use.