DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

March 7, 2016

Re: K153244
Trade/Device Name: Cios Fusion
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO
Dated: January 27, 2016
Received: January 28, 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,

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)*

K153244

Device Name

Cios Fusion

Indications for Use *(Describe)*

The Cios Fusion 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.

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510(k) Summary: Cios Fusion

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

Date Prepared: January 27, 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 AG / Siemens Healthcare GmbH
Roentgenstrasse 19 - 21
95478 Kemnath, Germany
Establishment Registration Number:
3002466018

Legal Manufacturer:
SIEMENS AG
Wittelsbacherplatz 2
80333 Muenchen, Germany

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. Subject Device Name and Classification:

Trade Name:	Cios Fusion
Device:	Image-Intensified Fluoroscopic X-Ray System,

Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Codes:	OWB, OXO
Secondary Product Code:	JAA
Submission Type:	Traditional 510(k)
Regulation Number:	892.1650
Device Class	2

4. Legally Marketed Predicate Devices:

Primary Predicate:

Trade Name:	Cios Alpha
510(k) Number:	K132094
Device:	Interventional Fluoroscopic X-Ray system
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	OWB
Secondary Product Code:	OXO
Submission Type:	Traditional 510(k)
Regulation Number:	892.1650
Device Class	2
Recall Information:	Z-1958-2015

Secondary Predicate:

Trade Name:	Siremobil C-06 (renamed: Arcadis Varic)
510(k) Number:	K040066
Device:	Image-intensified Fluoroscopic X-ray system, Mobile
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	OXO
Secondary Product Code:	JAA
Submission Type:	Traditional 510(k)
Regulation Number:	892.1650
Device Class:	2
Recall Information:	Z-0118-06; Z-0123-06; Z-0438/9-06

5. Device Description:

The Siemens Cios Fusion mobile fluoroscopy system is an image intensified fluoroscopic 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 Image Processing System, user controls and image storage devices (DVD, USB).

Interfaces are provided for optional devices such as external monitors, thermal printers, MP3 players, connections for 2D navigation systems, lithotripters or injectors, as well as wired and wireless DICOM network interfaces.

6. Indications for Use:

The Cios Fusion 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.

7. Substantial Equivalence:

The new device Cios Fusion is within the same classification regulation for the same indications for use as the Primary predicate Cios Alpha (K132094, cleared 3/11/2014). Other comparable properties of the subject device to the Primary predicate include X-Ray technology, Mechanical design, the Detector technology and Image processing. Similarly, the Indications for Use, X-Ray technology/Output power, and Mechanical design are compared to the Secondary predicate Siremobil C-06 (Arcadis Varic) (K040066, cleared 2/12/2004). Documentation is provided to support a claim of substantial equivalence to these Siemens' predicate devices.

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

The Siemens Cios Fusion design is based on the Siemens Cios Alpha (K132094) including the system control, flat panel detector technology and image processing functions. The mechanical design and X-ray technology/Output power is based on the Siemens Siremobil C 06 (ARCADIS Varic) (K040066).

The subject device has the same fundamental scientific technologies as the predicate devices. The technological comparison table below demonstrates the comparability of the technological characteristics of the new device and the currently cleared predicate devices. The modifications do not affect the intended use of the device.

The table below compares the main performance data of the subject device with the predicate devices to substantiate equivalence of the subject device and predicates.

Features / Technology	Subject Device Cios Fusion Siemens	Primary Predicate Cios Alpha K132094 Siemens	Secondary Predicate Siremobil C06 - ARCADIS Varic K040066 Siemens
Mobile fluoroscopic C-arm	Yes	Yes	Yes
X-ray tube	Stationary Anode 0.6 mm focal spot	Rotating Anode 0.3/0.5 mm focal spot	Stationary Anode 0.6 mm focal spot
Tube housing assembly with high frequency generator	Yes, same design	Yes	Yes, same design
kV Range	40 kV to 110 kV	40 kV to 125 kV	40 kV to 110 kV
Max power output	2.3 kW	12 kW 25 kW (optional)	2.3 kW
Pulsed fluoroscopy	3 mA to 25 mA	3 mA to 119 mA (12kW)	up to 23 mA
Beam limiting device	Yes, rectangular	Yes, rectangular	Yes, Iris collimator
X-Ray detector	Solid State Detector	Solid State Detector	Image Intensifier with Optics and TV System (CCD technology)
Detector active field size	20 cm × 20 cm 30 cm × 30 cm (optional)	20 cm × 20 cm 30 cm × 30 cm (optional)	ø 23 cm
Optional integrated dose measurement device	Yes	Yes	Yes
Matrix size	1024 × 1024 (20 cm × 20 cm detector) 1536 × 1536 (30 cm × 30 cm detector)	1024 × 1024 (20 cm × 20 cm detector) 1536 × 1536 (30 cm × 30 cm detector)	1024 × 1024
Displays	19” TFT Flat Screen Color Display Panels	19” TFT Flat Screen Display Panels, B/W or Color	19” TFT Flat Screen Display Panels, B/W or Color
2D Image post processing	Yes	Yes	Yes
Dose optimization / Siemens CARE program	Yes	Yes	Yes
User Interface	Yes, touch panels	Yes, touch panels	Yes, membrane keyboards
NaviLink 2D integrated navigation interface	Yes	No	Yes
Lithotripsy Interface	Yes	No	Yes
Injector interface	Yes	Yes	No

Features / Technology	Subject Device Cios Fusion Siemens	Primary Predicate Cios Alpha K132094 Siemens	Secondary Predicate Siremobil C06 - ARCADIS Varic K040066 Siemens
DICOM functionality	Yes	Yes	Yes

9. Testing to Voluntary Consensus Standards

The Siemens Cios Fusion has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed, that the Siemens Cios Fusion complies with the following 21 CFR Federal Performance Standards:

1020.30 Diagnostic X-Ray Systems and their major components
1020.31 Radiographic Equipment
1020.32 Fluoroscopic equipment
1040.10 Laser products and with

Also, the following relevant voluntary FDA Recognized Consensus Standards as listed in the table below:

Recog-nition Number	Product Area	Title of Standard	Reference Number and Date	Organization
19-4	General II (ES/EMC)	Medical electrical equipment - Part 1:General requirements for basic safety and essential performance	60601-1:2005	AAMI ANSI
19-1	General II (ES/EMC)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	60601-1- 2: 2007	IEC
12-210	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: 2008	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: 2010	IEC
12-202	Radiology	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures	60601-2-43: 2010	IEC
12-274	Radiology	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	60601-2-54: 2009	IEC

Recog-nition Number	Product Area	Title of Standard	Reference Number and Date	Organization
5-40	General I (QS/RM)	Medical devices - Application of risk management to medical devices	14971:2007	ISO
12-238	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: 2007	IEC
13-8	Software/ Informatics	Medical device software - Software life cycle processes	62304:2006	IEC
5-67	General I (QS/RM)	Medical devices - Application of usability engineering to medical devices	62366:2007	AAMI ANSI IEC
12-229	Radiology	Medical electrical equipment - Radiation dose documentation - Part1: Equipment for radiography and radioscopy	PAS 61910-1: 2007	IEC

10. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk Management is ensured via a Risk Analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice and relevant international standards. The following performance data were provided in support of the substantial equivalence determination:

11. Bench Testing:

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.

12. Non-Clinical Testing:

The detectors were evaluated according to the FDA guidance document "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"..

Validation activities have been performed at the System test level on production prototype devices by appropriately trained and knowledgeable

test personnel. System level validation and regression testing has been performed successfully, demonstrating that the device meets the acceptance criteria as noted in the system test plans. The verification and validation activities within the meaning of the Quality Regulation (21 CFR 820.30) confirmed design requirements are fulfilled, system functions as intended and the Cios Fusion performs as designed and does not raise new questions regarding safety and effectiveness. Therefore, when compared to the predicate devices the Cios Fusion supports a determination of substantial equivalence to the predicate devices.

13. 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.

14. Clinical Testing:

The Cios Fusion has been tested in a clinical environment with the objective to confirm that usability and image quality are adequate for its intended use. In this test Cios Fusion has been evaluated for about four weeks. More than 30 patients have been examined with the Cios Fusion in the course of Ortho/Trauma procedures. These procedures included examinations of the upper and lower extremities, shoulder, hip/pelvis, cervical spine and lumbar spine.

The Cios Fusion was found to provide a better, more detailed image quality as compared to the Secondary predicate device Arcadis Varic.

15. Electrical Safety and Electromagnetic Compatibility (EMC):

Electrical safety and EMC testing were conducted on the Cios Fusion, 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.

16. Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for

Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level of concern, since a malfunction or latent design flaw in the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

17. Conclusion as to Substantial Equivalence:

The Cios Fusion 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 Fusion does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as the predicate devices.