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

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

November 22, 2016

Re: K162971
Trade/Device Name: Multix Fusion Max
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 21, 2016
Received: October 25, 2016

Dear Ms. Adams:

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)*

K162971

Device Name
Multix Fusion Max

Indications for Use *(Describe)*

Multix Fusion Max system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion Max enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion Max system is not meant for mammography.

Multix Fusion Max uses a mobile(wired), or a fixed (integrated) or wireless digital detector for generating diagnostic images by converting x-rays into image signals. The Multix Fusion Max is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

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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SIEMENS Healthcare

510(k) Summary: Multix Fusion Max

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

Date Prepared: November 21, 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 Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Establishment Registration Number
2240869

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

Siemens Healthcare GmbH, Business Unit XP
Siemensstrasse 1
Forchheim, Germany 91301
Establishment Registration Number:
3004977335

2. Contact Person

Denise Adams, RAC
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355
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3. Device Name and Classification

Trade Name:	Multix Fusion Max
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

4. Legally Marketed Predicate Devices

Primary Predicate

Trade Name:	Multix Fusion
510(k) #:	K142049
Clearance Date:	December 18, 2014
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

Reference Predicate

Trade Name:	YSIO Max
510(k) #:	K133259
Clearance Date:	January 24, 2014
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

5. Device Description

The Multix Fusion Max Radiography X-ray system is a modular system of x-ray components (ceiling suspension with X-ray tube, Bucky wall stand, Bucky table, X-ray generator, portable wireless and integrated detectors) same as the predicate the Multix Fusion. This 510(k) submission describes modifications to the predicate device the Multix Fusion cleared via K142049.

The following modifications have been made to the cleared predicate device and the system will be rebranded the Multix Fusion Max:

Hardware
The following components are being integrated into the system: the Pixium 3543 EZh wireless detector, the Pixium 2430 EZ wireless detector; the Pixium 4343RCE fixed detector, a new wireless Bucky wall stand with motorized height adjustment, a new table that has a charging tray and a manual Bucky tray, and a new 92-line grid with a 13:1 ratio.

Software
The operating system is being upgraded from Windows XP to Windows 7 and the software version will now be VE21.

6. Indication for Use
Multix Fusion Max system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion Max enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion Max system is not meant for mammography.
Multix Fusion Max uses a mobile (wired), or a fixed (integrated) or wireless digital detector for generating diagnostic images by converting x-rays into image signals. The Multix Fusion Max is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

7. Substantial Equivalence
The Multix Fusion Max is a modification to the primary predicate device the Multix Fusion cleared via K142049. The Multix Fusion Max utilizes the same wireless detectors as the reference device the Ysio Max cleared via K133259. It is within the same classification regulation for the same indications for use and the same mechanical design as the predicate devices. The Multix Fusion Max is substantially equivalent to the predicate devices and documentation is provided to support a claim of substantial equivalence.

Comparison of Indications for Use

	Multix Fusion Max (subject)	**Multix Fusion K142049 (primary predicate)**	**Comparison Results**
Indications for Use	The Multix Fusion Max system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion Max enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting,	The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting,	**Same**

	standing, or in the prone position. The Multix Fusion Max system is not meant for mammography. The Multix Fusion uses a mobile (wired), or fixed (integrated) or wireless digital detector for generating diagnostic images by converting x-rays into image signals. The Multix Fusion is also designed to be used with conventional film/ screen or Computed Radiography (CR) cassettes.	standing, or in the prone position. The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired), or fixed (integrated) or wireless digital detector for generating diagnostic images by converting x-rays into image signals. The Multix Fusion is also designed to be used with conventional film/ screen or Computed Radiography (CR) cassettes.	

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Comparison of Subject Device to the Primary Predicate Device

Attribute	**Multix Fusion Max (subject)**	**Multix Fusion K142049 (primary predicate)**	**Comparison Results**
Ceiling mounted support (unchanged)	Semi-automated	Semi-automated	**Same**
X-ray tube assembly (unchanged)	80 kW Two-focus	80 kW Two-focus	**Same**
Collimator (unchanged)	Standard collimator(ACSS)	Standard collimator(ACSS)	**Same**
Patient Table	Radiographic table motorized with floating table top (wireless detector)	Radiographic table motorized with floating table top (wireless detector)	Charging tray
	Radiographic table motorized with floating table top (integrated detector)	Radiographic table motorized with floating table top (integrated detector)	**Same**
Bucky Wall Stand	BWS for integrated detector motorized height adjustment (vertical movement)	BWS for integrated detector motorized height adjustment (vertical movement)	**Same**

	BWS for wireless detector motorized height adjustment (vertical movement)	BWS for wireless detector motorized or manual height adjustment (vertical movement)	Only motorized height adjustment
Touch Interface (unchanged)	Graphical user interface	Graphical user interface	**Same**
X-ray generator (unchanged)	55kW, 65 kW or 80 kW	55kW, 65 kW or 80 kW	**Same**
Integrated detector TRIXELL	Pixium 4343RCE 43 cm x 43 cm	Pixium 4343RG 43 cm x 43 cm Pixium 4343RC 43 cm x 43 cm	Compared to the predicate Pixium 4343RC-the active area is smaller but the performance (e.g. DQE, MTF) is similar
Portable Wireless Detector (wi-D) TRIXELL	Pixium 3543EZh 43 cm x 35 cm Pixium 2430EZ 30 cm x 24 cm	PaxScan 4336W 43cm x 36 cm	Same technology with WIFI feature
Operating modes (unchanged)	RAD Single Exposure	RAD Single Exposure	**Same**
Imaging System (unchanged)	Fluorospot Compact PC based, high res digital	Fluorospot Compact PC based, high res digital	**Same**
Display 19" (unchanged)	Black & White or Color	Black & White or Color	**Same**
DICOM 3 Functions (unchanged)	Send, StC, Print, Query/Retrieve, Get Worklist, MPPS	Send, StC, Print, Query/Retrieve, Get Worklist, MPPS	**Same**
Radiographic Grid	92-line grid (ratio 13:1) 85-line grid (ratio 5:1) (optional)	80-line grid (ratio10:1) 50-line grid (ratio10:1)	More lines, different ratio
Accessory (unchanged)	Remote Control	Remote Control	**Same**

	console	console	

Fixed Subject Detector Compared to the Fixed Primary Predicate Detector

Technical Specifications	Trixell Pixium 4343RCE detector (fixed) (subject)	Trixell Pixium 4343RC detector (fixed) (predicate)	Comparison Results
Dimensions	423.3 mm x 425.4 mm	424.6 mm x 425.5 mm	Difference not significant
Resolution	2860 x 2874 pixels	2869 x 2874 pixels	Difference not significant
Pixel size	148 µm	148 µm	**Same**
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	**Same**
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
Acquisition depth	16 bit	16 bit	**Same**
DQE (Detective Quantum Efficiency)	DQE @ 0.05 lp/mm (2 µGy), 67%	DQE @ 0.05 lp/mm (2 µGy), 65%	Difference not significant
MTF (Modulations transfer function)	MTF @ 1 lp/mm, 62%	MTF @ 1 lp/mm, 63%	Difference not significant

Wireless Subject Detector Compared to the Wireless Primary Predicate Detector

Technical Specifications	Trixell Pixium 3543 EZh detector (wireless) (subject)	Varian PaxScan 4336W detector (wireless) (predicate)	Comparison Results
Dimensions	349 mm x 425 mm	356 mm x 427 mm	Smaller
Resolution	2356 x 2872 pixels	3032 x 2520 pixels	Difference not significant
Pixel size	148 µm	139 µm	Larger
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	**Same**
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
Acquisition depth	16 bit	16 bit	**Same**
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 50%	DQE @ 1 lp/mm (2 µGy), 54%	Difference not significant
MTF (Modulations transfer function)	MTF @ 1 lp/mm, 61%	MTF @ 1 lp/mm, 57%	Difference not significant

Wireless Subject Detector Compared to the Wireless Reference Predicate Detector

Technical Specifications	Trixell Pixium 3543 EZh detector (wireless) (subject)	Trixell Pixium 3543 EZh detector (wireless) (reference predicate)	Comparison Results
Dimensions	349 mm x 425 mm	349 mm x 425 mm	**Same**

Resolution	2356 x 2872 pixels	2356 x 2872 pixels	**Same**
Pixel size	148 µm	148 µm	**Same**
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	**Same**
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
Acquisition depth	16 bit	16 bit	**Same**
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 50%	DQE @ 1 lp/mm (2 µGy), 50%	**Same**
MTF (Modulations transfer function)	MTF @ 1 lp/mm, 61%	MTF @ 1 lp/mm, 61%	**Same**

Wireless Subject Detector Compared to the Wireless Primary Predicate Detector

Technical Specifications	**Trixell Pixium 2430EZ detector (wireless) (subject)**	**Varian PaxScan 4336W detector (wireless) (primary predicate)**	**Comparison Results**
Dimensions	228 mm x 284 mm	356 mm x 427 mm	Smaller
Resolution	1560 x 1920 pixels	3032 x 2520 pixels	Difference not significant
Pixel size	148 µm	139 µm	Larger
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	**Same**
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
Acquisition depth	16 bit	16 bit	**Same**
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 50%	DQE @ 1 lp/mm (2 µGy), 54%	Difference not significant
MTF (Modulations transfer function)	MTF @ 1 lp/mm,61%	MTF @ 1 lp/mm,57%	Difference not significant

Wireless Subject Detector Compared to the Wireless Reference Predicate Detector

Technical Specifications	**Trixell Pixium 2430EZ detector (wireless) (subject)**	**Trixell Pixium 2430EZ detector (wireless) (reference predicate)**	**Comparison Results**
Dimensions	228 mm x 284 mm	228 mm x 284 mm	**Same**
Resolution	1560 x 1920 pixels	1560 x 1920 pixels	**Same**
Pixel size	148 µm	148 µm	**Same**
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	**Same**
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
Acquisition depth	16 bit	16 bit	**Same**
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 50%	DQE @ 1 lp/mm (2 µGy), 50%	**Same**
MTF (Modulations transfer function)	MTF @ 1 lp/mm,61%	MTF @ 1 lp/mm,61%	**Same**

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

The Multix Fusion Max is comparable in indications for use, design, material, functionality, technology, energy source and is substantially equivalent to the commercially available predicates. It uses the same or similar components cleared in the Multix Fusion (e.g. tube, generator, ceiling-mounted tube support, table, Bucky wall stand and imaging system) and the Ysio Max (wireless detectors).

The components of the subject device have many of the same technological characteristics as the ones from the predicate devices. There are some technological characteristics that differ slightly as shown in the comparison tables.

Testing and validation have been successfully completed and test results show that the subject device Multix Fusion Max with all of its components are comparable to the predicate devices and therefore is substantially equivalent to the predicate devices.

The modifications made to the subject device Multix Fusion Max do not affect the intended use of the device nor do they alter its fundamental scientific technology from the 510(k) cleared predicate devices.

9. Nonclinical Performance Testing

Non-clinical tests were conducted for the Multix Fusion Max during product development. The modifications described in this Premarket Notification are supported with verification and validation testing.

Multix Fusion Max conforms to the following standards: IEC 60601-1:2012, ed.3.1; IEC 60601-1-2 3rd 2007; IEC 60601-1-3:2008+A1:2013; IEC 62366: 2014; ISO 14971:2007; IEC 62304 Ed. 1.1 2015; IEC 60601-2-28 Edition 2.0 (2010); IEC 60601-2-54 Edition 1.1 2015; PS 3.1 - 3.20 (2011); IEC 60601-1-6: 2013 and ISO 10993-1:2009.

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. Non-clinical tests (integration and functional) were conducted on the Multix Fusion Max during product development.

Detector integration testing consisted of functional and image quality tests. Functional tests included exposure workflow, detector sharing function and image resend functions. Image quality tests included flat field uniformity of the detector.

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.

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. Several safety features including visual and audible warnings are incorporated into the system design. In addition, the

Multix Fusion Max Radiography X-ray system is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.
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 X-ray examinations to be performed.

11. Conclusion as to Substantial Equivalence

The Multix Fusion Max has the same indications for use as the predicate Multix Fusion. The operating environment and mechanical design are similar. It is Siemens opinion, that the Multix Fusion Max is substantially equivalent to the Multix Fusion, cleared 12/18/2014 in K142049.

The predicate device was cleared based on non-clinical supportive information. Therefore, the subject device non-clinical data supports the safety of software with verification and validation testing. Verification and validation testing demonstrates that the Multix Fusion Max should perform as intended. The non-clinical test data demonstrate that the Multix Fusion Max device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens is of the opinion that the Multix Fusion Max does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate device.