Siemens Medical Solutions USA, Inc. June 19, 2019
Martin Rajchel
Regulatory Affairs Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN, PA 19355

Re: K191418
Trade/Device Name: Multix Fusion Max
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: May 24, 2019
Received: May 28, 2019

Dear Mr. Martin Rajchel:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191418

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.

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

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510(k) Summary: Multix Fusion Max

K191418

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

Date Prepared: May 24, 2019

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the 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, China 201318
Establishment Registration Number: 3003202425

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

2. Contact Person

Martin Rajchel
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
610-448-6545
martin.rajchel@siemens-healthineers.com

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 Device

Trade Name:	Multix Fusion Max
510(k) #:	K162971
Clearance Date:	November 22, 2016
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

Reference Device:	
Trade Name:	Ysio Max
510(k) #:	K181279
Clearance Date:	June 13, 2018
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) which is the same as the predicate device, the Multix Fusion Max (K162971). The portable wireless and integrated detectors used with Multix Fusion Max are imported from the cleared predicate device, Multix Fusion Max (K162971). There are no new imaging detectors added to the subject x-ray system. The Multix Fusion Max software is being used unchanged from the reference device, Ysio Max (K181279). This 510(k) submission describes modifications to the predicate device, the Multix Fusion Max, cleared via K162971.

The purpose of this submission is for the following modifications to Multix Fusion Max:

- Updated operating system from Windows 7 to Windows 10 and software version upgrade from VE21 to VF10
- New cybersecurity features
- Additional pediatric exposure technique factors

- A new 80-line grid with a 15:1 ratio
- The image processing algorithms (DiamondView MAX) will be used for exposures without grid
- The Multix Fusion Max with VF10 has been tested according to the currently recognized voluntary standards.

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 predicate device, Multix Fusion Max, cleared via K162971. The Multix Fusion Max utilizes the same operating system and same software version as the reference device, the Ysio Max, cleared via K181279. Multix Fusion Max is within the same classification regulation, has the same indications for use, and the same mechanical design as the predicate device. The Multix Fusion Max is substantially equivalent to the predicate device and documentation is provided to support a claim of substantial equivalence.

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

The Multix Fusion Max is substantially equivalent to the commercially available predicate device, the Multix Fusion Max (K162971) in terms of design, materials, functionality, technology, and energy source. The indications for use is the same as the commercially available predicate device, Multix Fusion Max (K162971). The subject device uses the same components cleared in the Multix Fusion Max (e.g. tube, generator, ceiling-mounted tube support, table, bucky wall stand, detectors, and imaging system).

The components of the subject device have many of the same technological characteristics as the ones from the predicate device. There are some technological characteristics that differ slightly as shown in the comparison tables below. Verification and validation testing has been successfully completed and test results show that the subject device, Multix Fusion Max, with all of its components, is substantially equivalent to the predicate device.

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 compared to the predicate device.

The following tables compare the main attributes of the subject device to the predicate device:

Table 1: Comparison of the Subject Device Multix Fusion Max to the Predicate – Indications for Use

	Multix Fusion Max (Subject)	**Multix Fusion Max K162971 (Predicate)**	**Comparison Results**
Indications 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	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	**Same**

	is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	Radiography (CR) cassettes.	

Table 2: Subject Device, Multix Fusion Max Attributes Compared to the Predicate

Attribute	Multix Fusion Max (Subject)	Multix Fusion Max K162971 (Predicate)	Comparison Results
Operating system	Windows 10	Windows 7	New operating system, does not affect safety or effectiveness
Digital imaging system (unchanged)	Fluorospot Compact	Fluorospot Compact	**Same**
Cybersecurity	Security package based on MS Win 10	Security package based on MS Win 7	Improved security package for the new operating system
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 (unchanged)	Radiographic table motorized with floating table top with charging in tray (wireless detector)	Radiographic table motorized with floating table top with charging in tray (wireless detector)	**Same**

	Radiographic table motorized with floating table top (integrated detector)	Radiographic table motorized with floating table top (integrated detector)	**Same**
Bucky Wall Stand (BWS) (unchanged)	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 height adjustment (vertical movement)	**Same**
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 (unchanged)	Pixium 4343RCE= Max Static 43 cm x 43 cm	Pixium 4343RCE= Max Static 43 cm x 43 cm	**Same**
Portable Wireless Detector TRIXELL (unchanged)	Pixium 3543EZh=Max Wi-D 43 cm x 35 cm Pixium 2430EZ= Max Mini 30 cm x 24 cm	Pixium 3543EZh=Max Wi-D 43 cm x 35 cm Pixium 2430EZ= Max Mini 30 cm x 24 cm	**Same**
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”	Color	Black & White or Color	Different, does not affect safety or effectiveness
DICOM 3 Functions	Send, StC, Print,	Send, StC, Print,	**Same**

(unchanged)	Query/Retrieve, Get Worklist, MPPS	Query/Retrieve, Get Worklist, MPPS	
Radiographic Grid	92-line grid (ratio 13:1) 85-line grid (ratio 5:1) (optional) 80-line grid (ratio 15:1)(optional)	92-line grid (ratio 13:1) 85-line grid (ratio 5:1) (optional)	New 80-line grid option to be used for specific organ programs (e.g., table side lateral exposures).
Accessory (unchanged)	Remote Control console	Remote Control console	**Same**
Image processing	DiamondView MAX	Diamond View Plus	**Same** (brand name change only)
Pediatric package	Increased number of organ programs	Organ programs	Increased number and variability

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: ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; IEC 60601-1-2:2014 ed. 4.0 2014-02; IEC 60601-1-3 Edition 2.1 2013-04; IEC 62366-1 Edition 1.0 2015-02; ISO 14971 Second edition 2007-03-01; IEC 60601-1-6 Edition 3.1 2013-10; IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION; IEC 60601-2-28 Edition 3.0 2017-06; IEC 60601-2-54 CONSOLIDATED VERSION Edition 1.1 2015-04; PS 3.1 - 3.20 (2016) and ISO 10993-1 Fourth edition 2009-10-15.

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.

The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The testing results indicate that all the software specifications have met the acceptance criteria. Verification and validation testing was found acceptable to support 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. 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 healthcare 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 device, Multix Fusion Max (K162971). The operating environment and mechanical design are similar. It is Siemens' opinion that the Multix Fusion Max is substantially equivalent to the Multix Fusion Max, cleared in K162971, November 22, 2016.

The predicate device was cleared based on non-clinical supportive information. Therefore, the subject device non-clinical data supports the safety of the device with verification and validation testing. Verification and validation testing demonstrates that the Multix Fusion Max performs 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.

12. Guidance documents

The following FDA guidance documents were utilized in this Premarket Notification:

- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document Issued on: October 2, 2014

- *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on July 11, 2016.

- *Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff*
  Document issued on November 28, 2017.

- *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: September 1, 2016

- *Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices*
  Document issued on: May 11, 2005

- *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: September 14, 2018

- *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: July 28, 2014

- *Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: August 14, 2013