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

January 11, 2019

Re: K182517
Trade/Device Name: MULTIX Impact
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: November 28, 2018
Received: November 29, 2018

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. 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,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182517

Device Name
MULTIX Impact

Indications for Use *(Describe)*

The MULTIX Impact system is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact 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 Impact system is not meant for mammography.

The MULTIX Impact uses digital detectors for generating diagnostic images by converting x-rays into image signals. The MULTIX Impact 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 Impact

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

Date Prepared: September 11, 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 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
Siemensstrasse 1
Forchheim, Germany 91301
Establishment Registration Number:
3004977335

2. Contact Person

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SIEMENS Healthineers

3. Device Name and Classification

Trade Name:	MULTIX Impact
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

5. Device Description

The MULTIX Impact Radiography X-ray system is a modular system of X-ray components (floor-mounted X-ray tube, Bucky wall stand, Bucky table, X-ray generator, portable wireless detectors) similar to the predicate the Multix Fusion Max. This 510(k) submission describes modifications to the predicate device the Multix Fusion Max cleared via K162971. The following modifications have been made to the cleared predicate device and the new system will be branded the MULTIX Impact:

1. A new 43×35cm Wireless detector, 3543DR
2. A new X-ray tube and a new generator
3. An optional 40 line grid with grid suppression algorithm
4. Wireless Remote Control Console
5. An optional All-in-one PC containing touch screen function
6. An optional positioning assistance camera
7. Upgrade software to VA10
8. Upgrade operator system from Windows XP to Windows 10

6. Indications for Use

The MULTIX Impact system is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact 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 Impact system is not meant for mammography.

The MULTIX Impact uses digital detectors for generating diagnostic images by converting X-rays into image signals. The MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

7. Substantial Equivalence

The MULTIX Impact is a modification to the predicate device the Multix Fusion Max cleared via K162971. It is within the same classification regulation with similar indications for use and the same mechanical design as the predicate device. The MULTIX Impact 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 Impact is comparable in indications for use, design, material, functionality, technology, energy source and is substantially equivalent to the commercially available Siemens' Multix Fusion Max. It uses the same or similar components cleared in the Multix Fusion Max (e.g. collimator, patient table, Bucky wall stand).

The components of the subject device have many of the same technological characteristics as the ones from the predicate device. There are several 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 Impact with all of its components are comparable to the predicate device and therefore is substantially equivalent to the predicate device.

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

The following tables compare the main performance data of the subject device with the predicate device to substantiate equivalence.

Table 1: Indications for Use Comparison

Attribute	**MULTIX Impact (subject)**	**Multix Fusion Max K162971 (predicate)**	**Comparison Results**
Indications for Use	The MULTIX Impact system is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact enables radiographic exposures of the whole body	The Multix Fusion Max system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion Max enables radiographic	Intended use is the same. Indications for use have been reworded to

	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 Impact system is not meant for mammography. The MULTIX Impact uses digital detectors for generating diagnostic images by converting X-rays into image signals. The MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	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. The Multix Fusion Max 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.	simplify.

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Table 2: Subject Device Compared to the Predicate

Attribute	MULTIX Impact (subject)	Multix Fusion Max K162971 (predicate)	Comparison Results
Operating System	Windows 10	Windows XP	New operating system, does not affect safety or effectiveness
Suppression algorithm for low line grid	The new 40 low line grid requires a suppression algorithm to suppress line artifacts	N/A	Performance testing concluded does not affect image quality.
Post-processing software	-Contrast -Detail -Latitude -Noise -WLShift -WWShift	-Amplification -Edge Enhancement -Harmonization -Noise Reduction -Center Shift -Width Factor	Performance testing concluded does not affect image quality.
Floor mounted support	Mechanical	N/A	Does not affect safety or effectiveness
X-ray tube assembly	80 kW Two-focus	80 kW Two-focus	**Same**
Collimator	Standard collimator (ACSS)	Standard collimator(ACSS)	**Same**
Optional collimator	Manual collimator	N/A	Does not affect safety or effectiveness
Optional digital camera	Camera on collimator to aid in patient positioning	N/A	Does not affect safety or effectiveness

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Attribute	MULTIX Impact (subject)	Multix Fusion Max K162971 (predicate)	Comparison Results
Patient Table	Radiographic table motorized with floating table top and motorized Bucky tray with charging in tray function (wireless detector)	Radiographic table motorized with floating table top and manual Bucky tray with charging in tray function (wireless detector)	Improvement of Bucky movement to motorized. Does not affect safety or effectiveness
	Radiographic table motorized with floating table top and motorized Bucky tray (wireless detector)	Radiographic table motorized with floating table top and manual Bucky tray with charging in tray function (wireless detector)	Improvement of Bucky movement to motorized without charging function in tray Does not affect safety or effectiveness
	Fixed radiographic table with floating table top and manual Bucky tray (portable wireless detector)	N/A	Does not affect safety or effectiveness
Bucky Wall Stand	BWS for wireless detector Vertical motorized and charging in tray	BWS for wireless detector Vertical motorized and charging in tray	**Same**
	BWS for wireless detector Vertical motorized	BWS for wireless detector Vertical motorized and charging in tray	No charging tray. Does not affect safety or effectiveness
	BWS for wireless detector Manual movement in z-axis	N/A	Does not affect safety or effectiveness

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Attribute	MULTIX Impact (subject)	Multix Fusion Max K162971 (predicate)	Comparison Results
Touch Interface	Graphical user interface	Graphical user interface	**Same**
X-ray generator	55kW, 65kW or 80kW	55kW, 65 kW or 80 kW	**Same**
Operating modes	RAD Single Exposure	RAD Single Exposure	**Same**
Imaging System	All in one PC based high resolution digital touch screen function as option	Fluorospot Compact PC based high resolution digital	Addition of touch screen function as option. Does not affect safety or effectiveness
Display	Black & White Color Size Ratio 16:9	Black & White Color Size Ratio 4:3	Different size ratio. Does not affect safety or effectiveness
DICOM 3 Functions	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) 40-line grid (ratio 13:1)	92-line grid (ratio 13:1) 85-line grid (ratio 5:1) (optional)	**Same ratio** with new addition of 40-line grid. Performance testing concluded that combined with suppression algorithm does not affect image quality
Accessory	Wireless Remote Control Console via bluetooth	Remote Control console	Improvement of wireless function. Does

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Attribute	MULTIX Impact (subject)	Multix Fusion Max K162971 (predicate)	Comparison Results
			not affect safety or effectiveness

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Table 3: Comparison of Trixell Pixium 3543 DR to the Predicate Trixell Pixium 3543 EZh

Technical Specifications	Trixell Pixium 3543 DR detector (wireless) (subject)	Trixell Pixium 3543 EZh detector (wireless) (subject)	Trixell Pixium 3543 EZh detector (wireless) (predicate)	Comparison Results
Dimensions	345 mm x 426 mm	348 mm x 424 mm	349 mm x 425 mm	Difference not significant
Resolution	2156 x 2662 pixels	2350 x 2866 pixels	2356 x 2872 pixels	Difference not significant
Pixel size	160 µm	148 µm	148 µm	Difference not significant/ **Same**
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	Amorphous silicon, a-Si	**Same**
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
Acquisition depth	16 bit	16 bit	16 bit	**Same**
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 51%	DQE @ 1 1p/mm (2 µGy), 51%	DQE @ 1 lp/mm (2 µGy), 51%	**Same**
MTF (Modulations transfer function)	MTF @ 1 lp/mm,62%	MTF @ 1 1p/mm, 63%	MTF @ 1 lp/mm,63%	Difference not significant/ **Same**

9. Nonclinical Performance Testing

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

MULTIX Impact conforms to the following standards: IEC 60601-1:2012; IEC 60601-1-2:2014; IEC 60601-1-3:2008+A1:2013; IEC 62366-1:2015; ISO 14971:2007; IEC 60601-1-6:2013; IEC 62304:2015; IEC 60601-2-28:2010-03; IEC 60601-2-54:2015-04; NEMA PS 3.1 - 3.20 (2016) 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 Impact 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.

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 Impact 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 Impact has similar indications for use as the predicate Multix Fusion Max. The operating environment and mechanical design are similar. It is Siemens opinion, that the MULTIX Impact is substantially equivalent to the Multix Fusion Max, cleared in K162971 on November 22, 2016.

Verification and validation testing demonstrates that the MULTIX Impact should perform as intended. The non-clinical test data demonstrate that the MULTIX Impact 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 Impact 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 the documentation of 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