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

March 20, 2020

Re: K193089
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: February 11, 2020
Received: February 12, 2020

Dear Mr. 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)*
K193089

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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K193089

510(k) Summary: MULTIX Impact

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

Date Prepared: November 5, 2019

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

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. Subject 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 Impact
510(k) #:	K182517
Clearance Date:	January 11, 2019
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

5. Device Description

The MULTIX Impact (VA11) 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 and fixed detectors) based on the predicate device, the MULTIX Impact (K182517). The following modifications have been made to the predicate device:

1. A new 43*43cm wireless detector, Mars1717VS manufactured by iRay
2. A new 43*43cm fixed detector, Venu1717X manufactured by iRay
3. A new Remote Interface used for patient examination management
4. Upgraded software version from VA10 to VA11 to support hardware modifications and Remote Interface.
5. New Bucky Wall Stands
6. New patient table

The new system will be branded as the MULTIX Impact.

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 (VA11) is a modification of the predicate device, the MULTIX Impact, cleared via K182517. The subject device is within the same classification regulation, has the same indications for use, and the same mechanical design as the predicate device. The MULTIX Impact (VA11) 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 (VA11) is substantially equivalent to the commercially available MULTIX Impact (K182517) in terms of the indications for use, design, material, functionality, technology, and energy source. The subject device uses the same or similar components cleared in the MULTIX Impact (e.g. tube, generator, collimator, patient table, Bucky Wall Stand, 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 have been successfully completed and test results show that the subject device, MULTIX Impact (VA11) with all its components, is substantially equivalent to the predicate device.
The modifications made to the subject device, MULTIX Impact (VA11), do not affect the intended use of the device nor do they alter its fundamental scientific technology compared to the predicate device, the MULTIX Impact (K182517).

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

Table 1: Indications for Use Comparison:

	MULTIX Impact VA11 (Subject)	MULTIX Impact K182517 (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 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.	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.	**Same**

Table 2: Subject Device Compared to Predicate

Attribute	MULTIX Impact VA11 (Subject)	MULTIX Impact K182517 (Predicate)	Comparison Results
SSXI for RAD imaging	Trixell Pixium 3543EZH	Trixell Pixium 3543EZH	**Same**
	iRay Mars1717VS with corresponding tray in bucky wall stand and patient table		Different. New flat detectors. Performance testing and co-existence testing concluded no impact on image quality.
	iRay Venu1717X with corresponding tray in bucky wall stand		
HMI (Human Machine Interface)	Touch user interface	Touch user interface	**Same**
	Remote Interface supported by Siemens provided tablet that meets minimum requirements.	N.A.	Different. New option. Performance testing and co-existence testing concluded no impact on safety and effectiveness.
UI (User Inteface) on Imaging System	- Color scheme is grey (dark) - Button shape is rounded or pill-shaped	- Color scheme is blue (dark) - Button shape is square	Different. Performance testing concluded no impact on safety and effectiveness.
Software version	VA11	VA10	Different. Improved to support hardware modifications and Remote Interface; Performance testing concluded no impact on safety and effectiveness.
Other minor modifications			

	MULTIX Impact VA11 (Subject)	K182517 (Predicate)	Comparison Results
Bucky Wall Stand (BWS)	For Pixium 3543 EZH: BWS with motorized height adjustment with new functions: - Option for fixed left or right direction to load the detector - Option for selectable left or right direction to load detector during installation	For Pixium 3543 EZH: BWS with motorized height adjustment - Standard configuration for fixed left or right direction to load detector	Different. Improved to support more operational possibilities. Performance testing concluded no impact on safety and effectiveness.
	For Mars1717VS: BWS with manual and motorized height adjustment with new functions - New tray for Mars1717VS - Option for fixed left or right direction to load detector - Option for selectable left or right direction to load detector during installation		Different. Modification to support the new detectors. Performance is unchanged. Testing concluded no impact on safety and effectiveness.
	For Venu1717X: BWS with motorized height adjustment with new functions - New tray for Venu1717X - Option for fixed left or right direction to load detector - Option for selectable left or right direction to load detector during installation - Additional emergency button and motion switch		
Patient table	Elevating Patient table in z-axis for Pixium 3543 EZH	Elevating Patient table in z-axis for Pixium 3543	**Same**

Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
usa.siemens.com/healthineers

	MULTIX Impact VA11 (Subject)	K182517 (Predicate)	Comparison Results
	Fixed and elevating Patient tables in z-axis for Mars1717VS: - new tray for new detector	EZH	Different. Modification to support the new detector. Performance is unchanged. Testing concluded no impact on safety and effectiveness.

Table 3: Comparison of iRay Flat Detectors to the predicate Trixell Pixium 3543EZh

Technical Specifications	iRay Mars1717VS (wireless) (Subject)	iRay Venu1717X (fixed) (Subject)	Trixell Pixium 3543EZH detector (wireless) (Predicate)	Comparison Results
	426 mm x 426 mm	426 mm x 426 mm	348 mm x 424 mm	Different. Minor change to size dimension only; no impact on safety and effectiveness.
	3070 x 3070 pixels	3070 x 3070 pixels	2350 x 2866 pixels	Different. Improved active area (larger) larger dimensions; no impact on safety and effectiveness.
	139 µm	139 µm	148 µm	Different. Minor change to pixel size only; no impact on safety and effectiveness.
Material	Amorphous	Amorphous	Amorphous	**Same**

	Cesium iodide (CsI)	Cesium iodide (CsI)	Cesium iodide (CsI)	**Same**
	16 bit	16 bit	16 bit	**Same**
Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 65%	DQE @ 1 lp/mm (2 µGy), 65%	DQE @ 1 lp/mm (2 µGy), 51%	Different. Minor improvement to DQE; no impact on safety and effectiveness.
(Modulations transfer function)	MTF @ 1 lp/mm, 64%	MTF @ 1 lp/mm, 64%	MTF @ 1 lp/mm, 63%	Different. Minor improvement to MTF; no impact on safety and effectiveness.

9. Nonclinical Performance Testing

Non-clinical tests were conducted for the MULTIX Impact (VA11) during product development. The modifications described in this Premarket Notification are supported with verification and validation testing.

MULTIX Impact (VA11) 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 60601-2-28:2017; IEC 60601-2-54:2015; 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 controls were implemented to mitigate identified hazards. The test results support 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 Impact (VA11) 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 Impact (VA11) has the same indications for use as the predicate device, MULTIX Impact. The operating environment and mechanical design are similar. It is Siemens opinion that the MULTIX Impact (VA11) is substantially equivalent to the MULTIX Impact, cleared in K182517 on January 11, 2019.

Verification and validation testing demonstrate that the MULTIX Impact (VA11) performs as intended. The non-clinical test data demonstrate that the MULTIX Impact (VA11) 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 (VA11) 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 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

Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
usa.siemens.com/healthineers