Siemens Medical Solutions USA, Inc.
% Denise Adams
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN PA 19355

May 17, 2022

Re: K220919
Trade/Device Name: MULTIX Impact E
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: March 28, 2022
Received: March 30, 2022

Dear Denise 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/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

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
and Electronic Products
OHT8: Office of 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)*
K220919

Device Name
MULTIX Impact E

Indications for Use *(Describe)*
MULTIX Impact E is a radiographic system used in hospitals, clinics, and medical practices.
MULTIX Impact E enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and obese patients. Exposures may be taken with the patient sitting, standing, or in the prone position.
MULTIX Impact E uses digital detectors for generating diagnostic images by converting X- rays into image signals.
MULTIX Impact E is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.
MULTIX Impact E is not intended for mammography.

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 E K220919

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: May 16, 2022

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
Malvern, PA 19355
Establishment Registration Number: 2240869

Manufacturer
Siemens Shanghai Medical Equipment Ltd.
278 Zhou Zhu Road
Shanghai, 201318, China
Establishment Registration Number: 3003202425

Contract Manufacturer
Siemens Healthcare GmbH
Siemensstrasse 1
Forchheim, Germany 91301
Establishment Registration Number: 3004977335

2. Contact Person

Denise Adams
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
610-448-6545
adams.denise@siemens-healthineers.com

3. Subject Device Name and Classification

Trade Name:	MULTIX Impact E
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 (VA20)
510(k) #:	K203345
Clearance Date:	March 20, 2020
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 E 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 detector) based on the predicate device, the MULTIX Impact (K203345). The following modifications have been made to the predicate device:

1) A new X-ray Tube Assembly
2) A new Collimator
3) A new Generator
4) Fixed patient table
5) Tube-side control module (TCM)
6) Upgraded software version to VB10 to support hardware modifications

The modified system will be branded as the MULTIX Impact E.

6. Indications for Use

MULTIX Impact E is a radiographic system used in hospitals, clinics, and medical practices.
MULTIX Impact E enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and obese patients. Exposures may be taken with the patient sitting, standing, or in the prone position.
MULTIX Impact E uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact E is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.
MULTIX Impact E is not intended for mammography.

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7. Substantial Equivalence

The MULTIX Impact E is a modification of the predicate device, the MULTIX Impact (VA20), cleared via K203345. The subject device is within the same classification regulation, has the similar indications for use, and the similar mechanical design as the predicate device. The MULTIX Impact E 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 E is substantially equivalent to the commercially available MULTIX Impact (K203345) in terms of the intended use, design, biocompatibility material, functionality, technology, and energy source. The subject device uses the same or similar components cleared in the MULTIX Impact (e.g. detector, BWS and imaging system).

The components of the subject device have many of the same technological characteristics as those in the predicate device. Some technological characteristics that differ slightly are shown in the comparison tables below. Verification and validation testing have been successfully completed and test results show that the subject device, MULTIX Impact E with all its components, is substantially equivalent to the predicate device.
The modifications made to the subject device, MULTIX Impact E, 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 (K203345).

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

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Table 1: Indications for Use Comparison:

Attribute	MULTIX Impact E VB10 (Subject)	MULTIX Impact VA20 K203345 (Predicate)	Comparison Results
Indications for Use	MULTIX Impact E is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact E enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and obese patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact E uses digital detectors for generating diagnostic images by converting X-rays into image signals. MULTIX Impact E is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes. MULTIX Impact E is not intended for mammography.	MULTIX Impact 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. MULTIX Impact is not intended for mammography. MULTIX Impact uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	**Same**

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Table 2: Subject Device Compared to Predicate

Attribute	MULTIX Impact E VB10 (Subject)	MULTIX Impact VA20 K203345 (Predicate)	Comparison Results
Detector	Wireless detector: Mars1717VS	Wireless detector: Mars1717VS	**Same**
Tube Stand (TS)	Integrated fully manual TS - Manual tube tilting - Manual longitudinal movement - Manual tube lifting	Independent semi-motorized TS - Manual tube tilting - Manual longitudinal movement - Motorized tube lifting	**Different.** New tube modified from motorized to manual for lower cost. Verification and Validation testing concluded no impact on safety and effectiveness.
X-ray Tube	RAY-12_3S tube with following key performance: -Heat capacity of anode: 170KJ (230kHU) -Input Power with Ref.300W: 54KW -Anode rotary frequency: 50/60 Hz (3000/3600 rpm)	RAY-14S_3F tube with following key performance: -Heat capacity of anode: 260KJ (350kHU) -Input Power with Ref.300W: 78KW -Anode rotary frequency: 150/180 Hz(≈ 8500 to 10800 rpm)	**Different.** Performance reduced for lower cost and low-end market. Verification and Validation testing concluded no impact on safety and effectiveness.
Collimator	Manual collimator with feedback following information to system: -Blade positions -Cu filter status	Manual collimator without any feedback information to system	**Different.** Function improved to support more operational possibilities. Verification and Validation testing concluded no impact on safety and effectiveness.
Generator	50KW high frequency X-ray Generator with line voltage 3-phase, 380V / 400V / 440V (50/60Hz), 480 V (60Hz)	55KW/65KW/80KW high frequency X-ray Generator with line voltage 3-phase, 380V / 400V / 440V (50/60Hz), 480 V (60Hz)	**Different.** Configuration reduced for lower cost and low-end market. Verification and Validation testing concluded no impact on safety and effectiveness.
	40KW high frequency X-ray Generator with line voltage 1-phase, 208-230V /(50/60Hz)	N.A.	**Different.** Modified to support more operational possibilities.

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Attribute	MULTIX Impact E VB10 (Subject)	MULTIX Impact VA20 K203345 (Predicate)	Comparison Results
			Verification and Validation testing concluded no impact on safety and effectiveness.
Automatic Exposure Control (AEC)	3 fields AEC chamber with analog interface to system	5 fields AEC module with CAN interface to system	**Different.** Modified for lower cost and low-end market. Verification and Validation testing concluded no impact on safety and effectiveness.
Patient Table	Fixed table with integrated rail mounting tube stand	Fixed table without rail	**Different.** Modified for lower cost and low-end market. Verification and Validation testing concluded no impact on safety and effectiveness.
Human Machine Interface (HMI)	Tube-side control module (TCM) with following functions: -SID display -Tube angle display -Release brakes	N.A.	**Different.** Modified to support more operational possibilities. Verification and Validation testing concluded no impact on safety and effectiveness.
	Touch User Interface module (TUI)	Touch User Interface module (TUI)	**Same**
	N.A.	Remote Interface supported by Siemens provided tablet that meets minimum requirements.	**Different.** Function reduced for lower cost and low-end market. Verification and Validation testing concluded no impact on safety and effectiveness.
UI (User Interface) on Imaging System	Siemens UI concept	Siemens UI concept	**Same**

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Attribute	MULTIX Impact E VB10 (Subject)	MULTIX Impact VA20 K203345 (Predicate)	Comparison Results
Software version	VB10	VA20	**Different** Updated to support all hardware modifications. Verification and Validation testing concluded no impact on safety and effectiveness.

9. Nonclinical Performance Testing

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

MULTIX Impact E conforms to the following standards: ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; IEC 60601-1-3:2013; IEC 60601-1-2:2014; IEC 62366-1:2015; ISO 14971:2019; IEC 60601-1-6:2013; IEC 62304:2015; IEC 60601-2-28:2017; IEC 60601-2-54:2018; NEMA PS 3.1-3.20 (2016) and ISO 10993-1:2018.

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 E 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 were 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 E 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 E has the similar indications for use as the predicate device, MULTIX Impact (K203345). The operating environment is same and mechanical design is similar.

Verification and validation testing demonstrate that the MULTIX Impact E performs as intended. The non-clinical test data demonstrate that the MULTIX Impact E device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens concludes that the MULTIX Impact E does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device, MULTIX Impact (K203345).

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

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