November 29, 2023

Siemens Medical Solutions
% Camila Rodriguez Valentin
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN, PA 19355

Re: K233532
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: November 2, 2023
Received: November 2, 2023

Dear Camila Rodriguez Valentin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233532

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**

510(k) Number: **K233532**

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

Date Prepared: October 30, 2023

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA of 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

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

Contract Manufacturing Site:
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Camila Rodriguez Valentin
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Alternate Contact Person:
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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
Secondary Product Code:	MQB

4. Legally Marketed Predicate Device:

Trade Name	**MULTIX Impact E**
Company	Siemens Medical Solutions USA
510(k) Number	K220919
Device Classification Name	Stationary X-Ray System
Regulation Number	21 CFR §892.1680
Review Panel	Radiology
Device Class	Class II
Product Code	KPR
Secondary Product Code:	MQB

5. Legally Marketed Reference Device:

Trade Name	**MULTIX Impact**
Company	Siemens Medical Solutions
510(k) Number	USA K213700
Device Classification Name	Stationary X-Ray System
Regulation Number	21 CFR §892.1680
Review Panel	Radiology
Device Class	Class II
Product Code	KPR
Secondary Product Code:	MQB

6. 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 E (VB10) (K220919). The following modifications have been made to the predicate device:

1) A new elevating table (option)
2) Upgraded software version to VB20 to support hardware modifications.

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

7. Indication 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.

8. Technological Characteristics and Substantial Equivalence:

The MULTIX Impact E is substantially equivalent to the commercially available MULTIX Impact E (VB10) (K220919) 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 (VB10) (e.g. detector, BWS and imaging system etc.).

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 E (VB10) (K220919).

Tables 8-1 and 8-2 compare the main performance data of the subject device with the predicate device and reference device.

Table 8-1: Comparison of the Subject Device (MULTIX Impact E) to the Predicate Device (MULTIX Impact E VB10)

Attribute	MULTIX Impact E (Subject)	MULTIX Impact VB10 K220919 (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 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	**Same**

Attribute	MULTIX Impact E (Subject)	MULTIX Impact E VB10 K220919 (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	Integrated fully manual TS - Manual tube tilting - Manual longitudinal movement - Manual tube lifting	**Same**

Attribute	MULTIX Impact E (Subject)	MULTIX Impact E VB10 K220919 (Predicate)	Comparison Results
	Independent fully manual TS - Manual tube tilting - Manual longitudinal movement - Manual tube lifting - Movement range: 33 ~ 180 cm	Integrated fully manual TS - Manual tube tilting - Manual longitudinal movement - Manual tube lifting - Movement range: 50 ~ 185 cm	**Similar** The movement range has been increased, Verification and Validation testing concluded no impact on safety and effectiveness.
X-ray Tube	RAY-12S_3 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-12S_3 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)	**Same**
Collimator	Manual collimator with feedback following information to system: -Blade positions -Cu filter status	Manual collimator with feedback following information to system: -Blade positions -Cu filter status	**Same**
Generator	50KW high frequency X-ray Generator with line voltage 3-phase, 380V / 400V / 440V (50/60Hz), 480 V (60Hz)	50KW high frequency X-ray Generator with line voltage 3-phase, 380V / 400V / 440V (50/60Hz), 480 V (60Hz)	**Same**
	40KW high frequency X-ray Generator with line voltage 1-phase, 208-230V/(50/60Hz)	40KW high frequency X-ray Generator with line voltage 1-phase, 208-230V/(50/60Hz)	**Same**
Automatic Exposure Control (AEC)	3 fields AEC chamber with analog interface to system	3 fields AEC chamber with analog interface to system	**Same**
Patient Table	Fixed table with integrated rail mounting tube stand	Fixed table with integrated rail mounting tube stand	**Same**

Attribute	MULTIX Impact E (Subject)	MULTIX Impact E VB10 K220919 (Predicate)	Comparison Results
	Elevating table (option) with independent rail mounting tube stand	N.A.	**Different** An elevating table (option) increases the clinical flexibility and versatility of the system enabling easy patient access and transfer. 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	Tube-side control module (TCM) with following functions: -SID display -Tube angle display -Release brakes	**Same**
	Touch User Interface module (TUI) -Rotation vertical axis (RVA) button is added in TUI Software	Touch User Interface module (TUI) -N.A.	**Similar** TUI software is updated for introducing the independent rail. Verification and Validation testing concluded no impact on safety and effectiveness.
UI (User Interface) on Imaging System	Siemens UI concept	Siemens UI concept	**Same**
Software version	VB20	VB10	**Different** Updated to support all hardware modifications. Verification and Validation testing concluded no impact on safety and effectiveness.

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Table 8-2: Comparison of the Subject Device (MULTIX Impact E) New Features to Reference Device (MULTIX Impact VA21)

Technical Specifications	MULTIX Impact E (Subject)	MULTIX Impact VA21 K213700 (Reference)	Comparison Results
Elevating Table	Motorized elevating table with manual movement bucky for beam centering	Motorized elevating table with motorized movement bucky for beam centering	**Different.** Function reduced for lower cost and low-end market. Verification and Validation testing concluded no impact on safety and effectiveness.
	Adjustable height: from 52 to 96 cm	Adjustable height: from 51.5 to 90 cm	
	No tracking between tube stand and bucky	Automatic tube tracking (table mode)	
	High weight capacity: 300 kg	High weight capacity: 300 kg	**Same**
	With Emergency stop	With Emergency stop	
	Option: Non-table	Option: Non-table	

9. Summary of Non-Clinical Tests:

The subject device was tested and complied with the voluntary standards listed in the table below:

Table 9: Non-clinical performance testing

Standards Development Organization and Reference Number	Title of Standard
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
IEC 60601-1-2 2020 Ed 4.1	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

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60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28, 2017	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54 Edition 2.0 2022-09	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1 2020 Ed 1.1	Medical devices – Application of usability engineering to medical devices
ISO 14971: 2019	Medical devices – application of risk management to medical devices
IEC 62304 2015, Ed.1.1	Medical device software - Software life cycle processes
IEC TR 60601-4-2 Edition1.0 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
NEMA PS 3.1 - 3.20 2021e	Digital Imaging and Communications in Medicine (DICOM) Set
ISO EN ISO 10993-1 Fifth edition 2018	Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process

Software Documentation level is Basic Documentation Level per FDA's Guidance Document *Content of Premarket Submissions for Device Software Functions*, issued on June 14, 2023, 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 same indications for use as the predicate device, MULTIX Impact E (VB10) (K220919). 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 E (VB10) (K220919).

12. Guidance documents

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

- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: September 27, 2023

- *Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on June 6, 2022.

- *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

- *Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: June 14, 2023

- *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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