December 13, 2021

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

Re: K213700
Trade/Device Name: MULTIX Impact; MULTIX Impact C
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: November 18, 2021
Received: November 23, 2021

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. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213700

Device Name
MULTIX Impact;
MULTIX Impact C

Indications for Use *(Describe)*
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.

MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C 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 C is not intended for mammography.
MULTIX Impact C uses digital detectors for generating diagnostic images by converting X- rays into image signals.
MULTIX Impact C 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.

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510(k) Summary: MULTIX Impact / MULTIX Impact C
K213700

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

Date Prepared: December 7, 2021

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

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

Denise Adams
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
610-944-2184
adams.denise@siemens-healthineers.com

3. Subject Device Name and Classification

Trade Name:	MULTIX Impact (VA21)
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

Trade Name:	MULTIX Impact C (VA21)
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/Reference Devices

Trade Name:	MULTIX Impact (VA20)
510(k) #:	K203345
Clearance Date:	January 07, 2021
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

Trade Name:	MULTIX Impact C (VA20)
510(k) #:	K203340
Clearance Date:	January 06, 2021
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

Trade Name:	YSIO X.pree
510(k) #:	K201670
Clearance Date:	October 21, 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 (VA21) Radiography X-ray system is a floor mounted, modular system of x-ray components (x-ray tube, bucky wall stand, patient table, x-ray generator, portable wireless and fixed detectors) based on the predicate device, the MULTIX Impact (VA20, K203345).

The MULTIX Impact C (VA21) Radiography X-ray system is a ceiling suspended, modular system of x-ray components (x-ray tube, bucky wall stand, patient table, x-ray generator, portable wireless and fixed detectors) based on the predicate device, the MULTIX Impact C (VA20, K203340).

The following modifications have been made to the predicate devices:

1. Upgrade software version from VA20 to VA21 to support the new features: Auto TOD Measurement, Auto Thorax Collimation, Virtual Collimation, Hybrid Image Documentation (HID).
2. New mobile UI: Smart Remote Control (SRC).
3. New accessory: myExam 3D Camera, to support the new software features.
   The myExam 3D Camera has been cleared in YSIO X.pree (K201670).

6. Indications for Use

MULTIX Impact:

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.

MULTIX Impact C:

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

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

7. Substantial Equivalence

MULTIX Impact (VA21):
MULTIX Impact (VA21) 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 same indications for use, and the same mechanical design as the predicate device. The MULTIX Impact (VA21) is substantially equivalent to the predicate device and documentation is provided to support a claim of substantial equivalence.

MULTIX Impact C (VA21):
MULTIX Impact C (VA21) is a modification of the predicate device, the MULTIX Impact C (VA20), cleared via K203340. 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 C (VA21) 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 subject devices are substantially equivalent to the predicate devices in terms of the indications for use, design, material, functionality, technology, and energy source. The subject devices use the same or similar components cleared in the predicate devices.

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 attached comparison table. Verification and validation testing have been successfully completed and test results show that the subject devices with all its components, is substantially equivalent to the predicate devices.

The modifications made to the subject devices do not affect the intended use of the device nor do they alter its fundamental scientific technology compared to the predicate devices.

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

Table 1: Indications for Use Comparison:

Attribute	MULTIX Impact (VA21) (Subject)	MULTIX Impact (VA20) K203345 (Predicate)	Comparison Results
Indications for Use	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.	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**

Attribute	MULTIX Impact C (VA21) (Subject)	MULTIX Impact C (VA20) K203340 (Predicate)	Comparison Results
Indications for Use	MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C 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 C is not intended for mammography. MULTIX Impact C uses digital	MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C 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 C is not intended for mammography. MULTIX Impact C uses digital	**Same**

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

Table 2: Subject Device Compared to Predicate Device

Attribute	MULTIX Impact (VA21) (Subject)	MULTIX Impact (VA20) K203345 (Predicate)	Comparison Results
	MULTIX Impact C (VA21) (Subject)	MULTIX Impact C (VA20) K203340 (Predicate)	
Generator	Polydoros RFX	Polydoros RFX	Same
X-ray Tube	RAY-14S_3F	RAY-14S_3F	Same
Collimator	- Collimator ML03 - Collimator ML04 - Collimator RFU	- Collimator ML03 - Collimator ML04 - Collimator RFU	Same
	- Collimator ML04 - Collimator RFU	- Collimator ML04 - Collimator RFU	
Detector	- Trixell Pixium 3543EZH (MAX wi-D) - iRay Mars1717VS (Core XL) - iRay Venu1717X (Core Static)	- Trixell Pixium 3543EZH (MAX wi-D) - iRay Mars1717VS (Core XL) - iRay Venu1717X (Core Static)	Same
Bucky wall stand	Manual or motorized vertical module	Manual or motorized vertical module	Same
	- Motorized vertical module - Manual tilting module	- Motorized vertical module - Manual tilting module	
Floor mounted tube stand (MULTX Impact)	Floor mounted semi-motorized - - Manual tube tilting - Manual longitudinal movement Floor mounted fully motorized - Manual tube tilting - Motorized tube lifting - Manual longitudinal movement - Motorized tube tilting - Motorized longitudinal	Floor mounted semi-motorized - Manual tube tilting - Manual longitudinal movement Floor mounted fully motorized - Manual tube tilting - Motorized tube lifting - Manual longitudinal movement - Motorized tube tilting - Motorized longitudinal	Same

Attribute	MULTIX Impact (VA21) (Subject) MULTIX Impact C (VA21) (Subject)	MULTIX Impact (VA20) K203345 (Predicate) MULTIX Impact C (VA20) K203340 (Predicate)	Comparison Results
Ceiling suspension tube stand (MULTX Impact C)	Ceiling suspension manual - Manual tube tilting - Motorized tube lifting Ceiling suspension motorized - Motorized tube tilting - Motorized tube lifting	Ceiling suspension manual - Manual tube tilting - Motorized tube lifting Ceiling suspension motorized - Motorized tube tilting - Motorized tube lifting	Same
All-in-one PC	- With touch screen - With non-touch screen	- With touch screen - With non-touch screen	Same
Patient table	Elevating patient table with tray for wireless or fixed detector	Elevating patient table with tray for wireless or fixed detector	Same
Imaging System	Software version: VA21 including new software features: Auto TOD Measurement, Auto Thorax Collimation, Virtual Collimation, and Hybrid Image Documentation (HID).	Software version: VA20	**Different** Improved to support more operational possibilities. Bench testing concluded no impact on safety and effectiveness.
HMI (Human Machine Interface)	Smart Remote Control (SRC) supported by Siemens provided Phone that meets minimum requirements.	Remote Interface supported by Siemens provided tablet that meets minimum requirements.	**Similar** Same software with similar hardware. Bench testing concluded no impact on safety and effectiveness.

Attribute	MULTIX Impact (VA21) (Subject) MULTIX Impact C (VA21) (Subject)	MULTIX Impact (VA20) K203345 (Predicate) MULTIX Impact C (VA20) K203340 (Predicate)	Comparison Results
Camera	3D Camera	2D Camera	**Different** Improved to support the new features of Auto TOD Measurement, Auto Thorax Collimation, Virtual Collimation, and Hybrid Image Documentation (HID) . Bench testing concluded no impact on safety and effectiveness.

Table 3: Comparison of new feature to reference device

Technical Specifications	MULTIX Impact / MULTIX Impact C (VA21) (subject)	YSIO X.pree (K201670) (reference)	Comparison Results
myExam 3D Camera	- Accessory - Model: Intel® RealSenseTM D400 series	- Accessory - Model: Intel® RealSenseTM D400 series	**Similar** Same model series; Same functionality; Bench testing concluded no impact on safety and effectiveness.
Auto Thorax Collimation	Exam range automatically planned for Thorax by 3D camera with manual adjustment	Exam range automatically planned for Thorax by 3D camera with manual adjustment	**Different** Same functionality; Similar clinical workflow; Bench testing concluded no impact on safety and effectiveness.
Virtual Collimation	Manually adjust collimation size on imaging system by 3D camera	Manually adjust collimation size on imaging system by 3D camera	**Different** Same functionality; Similar clinical workflow; Bench testing concluded no impact on safety and effectiveness.

9. Nonclinical Performance Testing

Non-clinical tests were conducted for the MULTIX Impact (VA21) and MULTIX Impact C (VA21) during product development. The modifications described in this Premarket Notification are supported with verification and validation testing.

MULTIX Impact (VA21) and MULTIX Impact C (VA21) conforms to the following standards:
ANSI ES60601-1:2005/(R)2012 and A1:2012
IEC 60601-1-2 Edition 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 Edition 1.2 2018-06 CONSOLIDATED VERSION
NEMA PS 3.1 - 3.20 (2016)
ISO 10993-1 Fifth edition 2018-08

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 (VA21) and MULTIX Impact C (VA21) 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, MULTIX Impact (VA21) and MULTIX Impact C (VA21) Radiography X-ray system are 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 (VA21) / MULTIX Impact C (VA21) has the same indications for use as the predicate device, MULTIX Impact (VA20, K203345) / MULTIX Impact C (VA20, K203340). The operating environment and mechanical design are similar.

Verification and validation testing demonstrate that the MULTIX Impact (VA21) and MULTIX Impact (VA21) performs as intended. The non-clinical test data demonstrate that the MULTIX Impact (VA21) and MULTIX Impact C (VA21) 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 (VA21) and MULTIX Impact (VA21) does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device, MULTIX Impact (VA20, K203345) and MULTIX Impact C (VA20, K203340).

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
Malvern, PA 19355
USA

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