Siemens Medical Solutions USA, Inc.
% Mr. Martin Rajchel
Senior Regulatory Affairs Specialist
40 Liberty Blvd.
Mail code: 65-1A
MALVERN PA 19355

January 6, 2021

Re: K203340
Trade/Device Name: 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 11, 2020
Received: November 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)*
K203340

Device Name
MULTIX Impact C

Indications for Use *(Describe)*
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 C

K203340

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

Date Prepared: November 11, 2020

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 Sites
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
Sr. Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
martin.rajchel@siemens-healthineers.com

3. Subject Device Name and Classification

Trade Name:	MULTIX Impact C
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
510(k) #:	K193089
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

Reference Devices:

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

Trade Name:	Multix Fusion Max
510(k) #:	K191418
Clearance Date:	June 19, 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 C Radiography X-ray system is a modular system of x-ray components (ceiling suspension with x-ray tube, bucky wall stand, bucky table, x-ray generator, and portable wireless and fixed detectors) based on the predicate device, the MULTIX Impact (K193089). The detectors for the subject device, MULTIX Impact C, are the same as the detectors of the predicate device. The following modifications have been made to the predicate device:

1. New ceiling suspension with motorized tube tilting support for ortho function and new ceiling suspension with manual tube tilting
2. Modified automatic collimator
3. New Bucky Wall Stand
4. Upgraded software version from VA11 to VA20 to support hardware modifications
5. Modified patient table
6. Modified touch user interface (TUI)
7. Modified wireless remote-control console (WRCC) with new control design

The new system will be branded as the MULTIX Impact C.

6. 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 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 C is a modification of the predicate device, the MULTIX Impact (K193089). 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 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

MULTIX Impact C is substantially equivalent to the commercially available predicate device, MULTIX Impact (K193089) 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, detectors 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 C with all its components, is substantially equivalent to the predicate device.
The modifications made to the subject device, MULTIX Impact C, 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 (K193089).

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 C (Subject)	MULTIX Impact K193089 (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 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.	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** (Minor grammatical changes only)

Table 2: Subject Device Compared to Predicate

Attribute	MULTIX Impact C (Subject)	MULTIX Impact K193089 (Predicate)	Comparison Results
Tube Stand (TS)	Ceiling mounted manual TS - Manual tube tilting - Motorized tube lifting	Floor mounted semi motorized TS - Manual tube tilting - Manual longitudinal movement - Motorized tube lifting	Improved to support more operational possibilities.
	Ceiling mounted motorized TS - Motorized tube tilting - Motorized tube lifting		
Ortho function (option)	Hardware: Ortho Support	N.A.	New option to support more operational possibilities.
	Software: three options as below - Smart Ortho - Smart Virtual Ortho - Auto Full-Spine & Long-Leg Collimation	N.A.	
Collimator	Automatic collimator	Automatic collimator	**Same**
	N.A.	Manual collimator	New option
	Modified automatic collimator	N.A.	
Bucky Wall Stand (BWS)	New BWS with motorized height adjustment - 5 field AEC - Option for detector unit with motorized lifting scope of 315mm~1750mm - Detector unit with manual tilting	BWS with manual or motorized height adjustment - 3 field AEC - Option for detector unit with manual or motorized lifting scope of 330mm~1800mm	Improved to support more operational possibilities.
Imaging System	Detectors - Trixell MAX wi-D= Pixium 3543EZh - iRay Core XL=Mars1717VS - iRay Core Static=Venu1717X	Detectors - Trixell MAX wi-D= Pixium 3543EZh - iRay Core XL=Mars1717VS - iRay Core Static=Venu1717X	**Same**
	Software version: VA20	Software version: VA11	New software version with features like Ortho function, SmartPositioning, and modifications to support hardware changes

Attribute	MULTIX Impact C (Subject)	MULTIX Impact K193089 (Predicate)	Comparison Results
	User interface: - Operation Tabs are on the top area	User interface: - Operation Tabs are on the right sidebar	Improved appearance of user interface.
Other minor modifications			
Patient table	Elevating patient table with - 5 field AEC - Tray for wireless or fixed detector	Fixed or elevating patient table with - 3 field AEC - Tray for wireless detector	Improved to support more operational possibilities.
Touch User Interface (TUI)	Touch user interface - physical button with software indicator - Modified user interface for Ortho function	Touch user interface - physical button with silkscreen	Improved to support more operational possibilities.
Wireless Remote Control Console (WRCC)	Wireless Remote-Control Console（WRCC） - Collimation control - BWS lifting control - Enabled tracking - Tube stand motion (lifting) control - SmartPositioning button - Light localizer button	Wireless Remote-Control Console（WRCC） - Collimation control - BWS lifting control - Enabled tracking - Light localizer button	Improved to support more operational possibilities.

Table 3: Comparison of the Ortho function to the reference device

Function \ Product		MULTIX Impact C (Subject)	YSIO X.pree (K201670) (reference)	Comparison Results
Hardware		Ortho Support(Ortho Stand)	Ortho Support(Ortho Stand)	Same
Software (optional license keys)	Smart Ortho	Tilting Ortho: Ortho range set by adjusting collimator and tube tilt manually	Tilting Ortho: Ortho range set by adjusting collimator and tube tilt manually	New option to support more operational possibilities.
	Smart Virtual Ortho	Ortho range set by 2D camera in the image system manually	Ortho range set by 3D camera in the image system manually	
	Auto Full-Spine & Long-Leg Collimation	Otho range automatically planned for Full-Spine & Long-Leg by 2D camera with manual adjustment	Otho range automatically planned for Thorax by 3D camera with manual adjustment	

Table 4: Comparison of the Tube Stand to the reference device

Attribute	MULTIX Impact C (Subject)	Multix Fusion Max K191418 (reference)	Comparison Results
Tube Stand (TS)	Ceiling mounted manual TS - Manual tube tilting - Motorized tube lifting	Ceiling mounted semi-motorized TS - Manual tube tilting - Motorized tube lifting	New option to support more operational possibilities.
	Ceiling mounted motorized TS - Motorized tube tilting - Motorized tube lifting		

9. Nonclinical Performance Testing

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

MULTIX Impact C conforms to the following standards: ES60601-1:2005/(R)2012 and A1:2012; IEC 60601-1-3:2008+A1:2013; IEC 60601-1-2:2014; IEC 62366-1:2015; ISO 14971:2007; 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 10993-1:2009.

All components of the x-ray system MULTIX Impact C were tested and found adequate. All test results are a pass and support our claim of device safety and effectiveness.

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 C 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 C 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 C has the same indications for use as the predicate device, MULTIX Impact (K193089). The operating environment and mechanical design are similar.

Verification and validation testing demonstrate that the MULTIX Impact C performs as intended. The non-clinical test data demonstrate that the MULTIX Impact C 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 C does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate device, MULTIX Impact (K193089).

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