July 25, 2023

Siemens Medical Solutions USA, Inc.
℅ Camila Rodriguez Valentin
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN PA 19355

Re: K231577
Trade/Device Name: MOBILETT Impact
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: May 31, 2023
Received: May 31, 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 (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231577

Device Name
MOBILETT Impact

Indications for Use *(Describe)*
MOBILETT Impact is a mobile device intended to visualize anatomical structures of human beings by converting an X-ray pattern into a visible image. MOBILETT Impact is not intended for mammography examinations.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: **Mobilett Impact**

510(k) Number: **K231577**

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

Date Prepared: May 31, 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 Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Camila Rodriguez Valentin
Regulatory Affairs Professional
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Alternate Contact Person:

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3. Subject Device Name and Classification:

Trade Name:	**MOBILETT Impact**
Classification Name:	System, X-ray, Mobile
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1720
Device Class:	II
Product Code:	IZL

4. Legally Marketed Predicate Device:

Trade Name	**SM-V**
Company	SEDECAL SA
510(k) Number	K222951
Device Classification Name	System, X-ray, Mobile
Regulation Number	21 CFR §892.1720
Review Panel	Radiology
Product Code	IZL
Device Class	II

5. Legally Marketed Reference Device:

Trade Name	**MULTIX Impact**
Company	Siemens Shanghai Medical Equipment Ltd.
510(k) Number	K213700
Device Classification Name	Stationary X-Ray System
Regulation Number	21 CFR §892.1680
Review Panel	Radiology
Product Code	KPR
Device Class	II

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6. Device Description:

MOBILETT Impact is a complete X-ray imaging system on wheels. It contains a single tank high voltage generator with an X-ray tube and collimator attached to the end of a telescopic support arm connected to a swiveling column.

The system is a manually driven system, with no motor support for movement. The system includes a digital image acquisition system with an image display and graphical user interface. The digital detector, Max wi-D can be stored in the built-in docking station in the system. In addition, the system can be used with detectors Max mini and Core-L.

All three detectors are equipped with rechargeable batteries, which can be charged by external battery chargers. The system can perform X-Ray when it is connected to mains. Exposure can be released by a hand switch or remote control. The included system batteries only power the imaging system if it is not connected to the mains.

Besides the detectors and image system, the hardware of the system is the same as for the predicate device SEDECAL SM-V, which was cleared on 11/21/2022 with K222951.

7. Indication for Use:

MOBILETT Impact is a mobile device intended to visualize anatomical structures of human beings by converting an X-ray pattern into a visible image. MOBILETT Impact is not intended for mammography examinations.

8. Technological Characteristics and Substantial Equivalence:

MOBILETT Impact and its predicate device SM-V, K222951, are mobile X-ray systems within the same classification regulation, design, functionality, technology, and energy source. The subject device has similar intended use as the predicate device (SM-V) and components cleared in the predicate device (SM-V) and reference device (MULTIX Impact VA21). Mobilett Impact uses a software of Moderate Level of Concern (LOC) based on the predicate device (SM-V).

While some technical characteristics of the subject device differ slightly from those of the predicate device and reference device, verification and validation testing have demonstrated that the subject device and all its components are substantially equivalent to the predicate device. These variations do not impact the device's intended use or alter its fundamental scientific technology compared to the predicate device or reference device.

MOBILETT Impact is substantially equivalent to the predicate device, SM-V. Tables 8-1 and 8-2 compare the proposed subject device side-by-side with the predicate and reference devices.

Table 8-1: Comparison of the Subject Device (Mobilett Impact) to the Predicate Device (SM-V)

Feature	Predicate device SM-V	Subject device Mobilett Impact	Comment
Regulation Description	System, X-Ray, Mobile	System, X-Ray, Mobile	**Same**
Regulation Number	892.1720	892. 1720	**Same**
Classification Product Code	IZL	IZL	**Same**
Indications for use	This is a mobile diagnostic x-ray system intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.	Mobilett Impact is a mobile device intended to visualize anatomical structures of human beings by converting an X-ray pattern into a visible image. Mobilett Impact is not intended for mammography examinations.	**Similar**
Configuration	Mobile X-Ray system without digital flat detector and image system.	Mobile X-Ray system with digital flat detector and image system.	**Different.** Digital flat detector and image system added.
High voltage generator	16, 20, 32 KW Monoblock generator	16, 20, 32 KW Monoblock generator	**Same**
X-Ray Tube	SEDECAL, type CC01654	SEDECAL, type CC01654	**Same**
Tube voltage	40 kV to 150 kV	40 kV to 150 kV	**Same**
Tube current	0.32 mAs to 200 mAs	0.32 mAs to 200 mAs	**Same**
Collimator	Varex Optica 10	Varex Optica 10	**Same**
Touch screen control	19” touch display	19” touch display	**Same**
Movement	Non-motorized movement	Non-motorized movement	**Same**
US Performance Standard	21 CFR 1020.30	21 CFR 1020.30	**Same**
Power Source	Universal power supply, from 100 V~ to 240 V~. 1 phase	Universal power supply, from 100 V~ to 240 V~. 1 phase	**Same**
Imaging software	Not included	Impact Imaging System (IIS)	**Different.** Digital Imaging

			system added
Size	123 x 59 x 191 cm (including column) / 123 x 59 x 126 cm	123 x 59 x 191 cm (including column) / 123 x 59 x 126 cm	**Same**
Weight	275 kg	275 kg	**Same**
Digital detectors	Not included	Trixell Pixium 3543EZh (Max wi-D) Trixell Pixium 2430EZ (Max mini) iRAY Mars 1417VS (Core L)	**Different.** Digital Flat detectors have been added

Table 8-2: Comparison of the Subject Device (Mobilett Impact) to the Reference Device (Multix Impact) – Detector and Imaging System

Feature	**Predicate device** **Multix Impact**	**Subject device** **Mobilett Impact**	**Comment**
Detector	- Trixell Pixium 3543 EZh (MAX wi-D) - iRay Mars 1717VS (Core XL) - iRay Venu1717X (Core Static)	- Trixell Pixium 3543EZh (MAX wi-D) - Trixell Pixium 2430EZ (Max Mini) - iRay Mars 1417VS (Core L)	**Same.** Trixell Pixium 3543 EZh is the same **Different.** Trixell Pixium 2430 EZ is already used with other Siemens systems (see K221218, K201670, K181229, K173639) **Different.** iRay Mars 1417VS newly added.
Imaging System	Impact Imaging System (IIS)	Impact Imaging System (IIS)	**Same**
Display	With and without touch screen (Options) Ratio 16:9	With touch screen Ratio 4:3	**Similar** MOBILETT Impact is only available with touch screen

9. Summary of Non-Clinical Tests:

The MOBILETT Impact 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 60601-1, 2012 Ed. 3.1	Medical Electrical Equipment - Part 1: General Requirements for Safety
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
IEC 60601-1-3: Edition 2.1, 2013	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 2018, Edition 1.2	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 2013 Ed 3.1	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 61910-1: 2014, Ed 1.0	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy
NEMA PS 3.1 - 3.20 2021	Digital Imaging and Communications in Medicine(DICOM) Set

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ISO EN ISO 10993-1 Fifth edition 2018	Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirement Specification Reviews
- Design Reviews
- Integration testing (System verification and validation)

10. Summary of Clinical Tests:

A Customer Use Test (CUT) was performed at three hospitals to ensure the acceptance of the design and to gather feedback on the device's usability in the clinical environment.
The focus of the test was:

- System function and performance-related clinical workflow
- Image quality
- Ease of use
- Overall performance and stability

The clinical test results stated that the system's intended use was met, and the clinical need was covered.

11. General Safety and Effectiveness Concerns:

The Instructions for Use (IFU) are included within the device labeling, and the information provided enables the user to operate the device safely and effectively. Several safety features, including visual and audible warnings, are incorporated into the system design. In addition, the device is continually monitored, and if an error occurs, the system functions will be blocked, and an error message will be displayed.

Furthermore, the operators are healthcare professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

12. Conclusion as to Substantial Equivalence:

MOBILETT Impact is substantially equivalent to the predicate device SM-V (technical characteristics and performance with similar indications for use). The operating environment is the same, and the technology differences do not affect safety and effectiveness. Siemens concludes, according to this submission material and the documentation provided, that the MOBILETT Impact is substantially equivalent to the predicate device.

13. Guidance documents

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

Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography
Document issued on October 20, 2006

Content of Premarket Submission 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

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 MedicalDevices - Guidance for Industry and Food and Drug Administration Staff
Document issued on September 14, 2018.

The 510(k) Program: Evaluation Substantial Equivalent in Premarket Notifications 510(k) - Guidance for Industry and Food and Drug Administration Staff
Document issued on July 28, 2014.

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

Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document issue on August 13, 2013

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