Siemens Medical Solutions USA, Inc.
% Kim Rendon
Senior Manager, Regulatory Affairs
40 Liberty Boulevard, 65-1A
MALVERN PA 19355

March 15, 2019

Re: K182639
Trade/Device Name: MOBILETT Elara Max
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: February 5, 2019
Received: February 6, 2019

Dear Kim Rendon:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182639

Device Name
MOBILETT Elara Max

Indications for Use *(Describe)*
MOBILETT Elara Max is a mobile device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. MOBILETT Elara Max enables radio-graphic exposures of the whole body and may be used on pediatric, adult and bariatric patients. It can also be used for emergency applications.
MOBILETT Elara Max is not indicated for mammographic imaging.

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: MOBILETT Elara Max - K182639

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

Date Prepared: March 14, 2019

This 510(k) summary of safety and effectiveness information is being submitted in accordance with 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 S.A.
   Parque Empresarial La Carpetana,
   Avenida Leonardo da Vinci, 15
   E-28906 Getafe (Madrid), Spain
   Establishment Registration Number: 1000342169

2. **Contact Person:**
   Kim Rendon
   Sr. Regulatory Affairs Manager
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard, 65 – 1A
   Malvern, PA 19355
   Alternate Contact Person:
   Martin Rajchel
   Regulatory Affairs Specialist

3. **Device Name and Classification:**
   Trade Name: MOBILETT Elara Max
   Classification Name: System, X-ray, Mobile
   Classification Panel: Radiology
   Classification Regulation: 21 CFR §892.1720
   Device Class: II
   Product Codes: IZL

4. **Legally Marketed Predicate Device:**

   Trade Name: MOBILETT MIRA

510(k) Number: K111912
Device Classification Name: System, X-ray, Mobile
Regulation Medical Specialty: Radiology
Review Panel: Radiology
Product Code: IZL
Submission Type: Special 510(k)
Regulation Number: 892.1720
Device Class: II

5. Device Description:

The MOBILETT Elara Max is a mobile X-ray system with a solid state x-ray imager (SSXI). The system is designed to provide X-ray imaging by healthcare professionals. Rechargeable batteries support cable less operation and motor-driven movements to the point of care. The mobile generator is positioned at bedside and the X-ray system is directed to the anatomical area to be imaged. The image detector is placed perpendicular to the central beam behind this anatomical area. The system features a collimator with a light field that mimics the x-ray field to limit the field of exposure to the area to be imaged. Exposure may be released via remote control. The image data acquired by the detector are send wireless to the mobile unit.

The purpose of this submission is a new software version VF10, some minor hardware changes and the new device name MOBILETT Elara Max. The new software VF10 will introduce the following new features:

- The operating system will be MS Windows 10
- New cybersecurity features
- Additional pediatric programs
- Implementing a "Virtual Machine" that supports hospital IT
- The SSXIs have been updated
- The EMC (Electromagnetic Compatibility was tested according to the IEC 4th edition)
- The image processing algorithms (Diamond View MAX) will be used for exposures without grid.
- The Mobilett Elara will be coated with an anti-microbial paint

Once cleared new deliveries of the predicate MOBILETT Mira Max will have the VF10 SW. The hardware changes are for the MOBILETT Elara Max only. The HW changes include changes to the body to provide more protection for the tube housing assembly and the system is coated with a new anti-microbial paint.

6. Indications for Use:

MOBILETT Elara Max is a mobile device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. MOBILETT Elara Max enables radio-

graphic exposures of the whole body and may be used on pediatric, adult and bariatric patients. It can also be used for emergency applications.
MOBILETT Elara Max is not for mammography examinations.

7. Substantial Equivalence:

The new system software VF10 does not alter the intended use or the fundamental scientific technology. The device remains within the same classification regulation for the same intended use as the predicate device. The new system software design was completed in accordance with Siemens Quality Management System Design Controls comparable to the processes available for the predicate device. The scope of internationally recognized standards compliance was updated to the standards recognized at the time of the design of the new software. Verification and Validation testing was the same or similar to the testing being used with the predicate device.

The new system software version VF10 controls solid state X-ray imagers (SSXI) similar to the imagers being used with the predicate device. The updated Max wi-D and Max mini detectors have been previously cleared with K173639 and K181279.

The anti-microbial paint was previously cleared with the Siemens Artis Pheno (K163286). The Siemens Artis Pheno is referred to as a reference device.

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The subject device with the new software version VF10 uses the same X-ray generator, the same X-ray tube and similar SSXIs with the same digital imaging system and similar image processing software as the predicate device. There are no changes in the patient environment or the type of user interface.

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

Table 1: Comparison of the Subject Device MOBILETT Elara Max to the Predicate

	Subject Device	**Predicate Device**	
Feature	**MOBILETT Elara Max**	**Mobilett Mira K111912**	**Comparison Results**
Indications for Use Comparison			

Indications for Use statement	MOBILETT Elara Max is a mobile device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. MOBILETT Elara Max enables radio-graphic exposures of the whole body and may be used on paediatric, adult and bariatric patients. It can also be used for emergency applications.	The Mobilett Mira is a radiographic system designed for use in wards, intensive care and premature-birth wards, pediatric and emergency departments, operating theatres as well as the central X-ray department.	Indication for use described more clearly.
Technical Comparison			
X-ray			
Generator			Same technology
Max. output	35 kW	35 kW	
	40kV to 133kV	40kV to 133kV	
X-ray tube	Siemens P135/30R	Siemens P135/30 R	
Collimator	Manually adjustable multileaf collimator, rotable ±90°	Manually adjustable multileaf collimator, rotable ±90°	
Air kerma	Kerma X	Kerma X	
X-ray techniques	Radiography	Radiography	
Organ programs	X-ray parameters Imaging processing parameters. More programs for pediatric use	X-ray parameters Imaging processing parameters	
Testing			
IEC Compliance	IEC 4th edition for EMC testing	IEC 3rd edition for EMC testing	Testing according to current IEC test scope
Digital Imaging			
Wireless SSXI for Rad imaging	Trixell Pixium MAX wi-D = 3543EZh MAX mini = 2430EZ	Trixell Pixium 3543pR 2430EZ	Image Chain is similar to predicate device Detector Performance data according To SSXI guidance are provided
Digital imaging system	Fluorospot Compact	Fluorospot Compact	
Image processing	Diamond View MAX	Diamond View Plus	Same processing algorithms

MS Operating system	Windows 10	Windows XP	New Operating system
Cybersecurity	Security package based on MS Win 10	Security package based on MS Win XP	Improved
Integration of hospital IT	Hospital/Radiology Information System	Hospital/Radiology Information System	Improved
Pediatric package	Increased number of organ programs	Organ programs	Increased number and variability
Other			
X-ray "ON" lite	LED panels on suspension arm	Yellow light on user panel	Improved visibility
	Subject Device	**Reference Device**	
Feature	**MOBILETT Elara Max**	**Siemens Artis Pheno K163286**	**Comparison Results**
Body coating	Anti-microbial paint	Anti-microbial paint	Same paint as reference device

Summary of Non-Clinical Test Data:

The software VF10 design was completed in accordance with Siemens Quality Management System. Design Controls and verification and validation testing were successfully conducted. Non-clinical performance data are provided for the updated detectors. The new IEC 4th edition has been applied for the compliance to the IEC 60601-1-2 electromagnetic compatibility standard.

The tests were performed on the new software VF10 demonstrating that the device is safe and effective, performs comparably to the predicate device, and is substantially equivalent to the predicate device/reference device.

Documentation provided demonstrates compliance of the subject device to all FDA requirements stated in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation tests of software requirements and software risk hazards.

Performance testing confirmed that the device complies with 21 CFR 1020.30-31 Federal Performance Standards for X-Ray Radiographic equipment.

The software VF10 controls solid state X-ray imagers (SSXI) that are similar in performance to the predicates. Performance data are provided according to the "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, issued on: September 1, 2016". X-ray geometry

and techniques are the same so that clinical image comparisons involving SSXI were not conducted.

Together, the verification/validation activities successfully confirmed that the software requirements have been fulfilled and that system functionality is consistent with the user needs and intended uses. The VF10 software correctly performs as designed and raises no new questions regarding safety or effectiveness. Therefore, when compared to the predicate device the MOBILETT Elara Max with the new software VF10 supports a determination of substantial equivalence to the predicate device.

9. Summary of Non-Clinical Tests

The devices operating with software VF10 comply with the voluntary standards as listed in the following table:

Table 2: Standards

Development Organization and Reference Number	Title of Standard
IEC 60601-1:2012, Edition 3.1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2, Edition 4.0 2014-02	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 2013-04	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 62366, 2015	Medical devices – Application of usability engineering to medical devices
ISO 14971, 2007	Medical devices – application of risk management to medical devices
IEC 62304 Ed. 1.0, 2006	Medical device software - Software life cycle processes
IEC 60601-2-28, Edition 2.0 2010-03	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 1.0 2009	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 61910-1, 2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy (IEC 61910-1:2014)
NEMA PS 3.1 - 3.20, 2016	Digital Imaging and Communications in Medicine (DICOM) Set
ISO 10993-1, 2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

Documentation provided demonstrates compliance of the subject devices to all FDA requirements stated in the Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, including results of verification/validation tests of software requirements and software risk hazards.

Performance testing confirmed that the MOBILETT Elara Max with VF10 complies with 21 CFR 1020.30-31 Federal Performance Standards for X-Ray Radiographic equipment. The applicable sections include:

1020.30(c)	Manufacturer's Responsibility (Certification)
1020.30(e)	Identification of X-ray components
1020.30(g)	Information to be provided to assemblers
1020.30(h)	Information to be provided to users
1020.31(k)	Leakage Radiation
1020.30(m)	Beam Quality
1020.31(a)	Peak Tube Potential
1020.31 (d)(2)(i, iii)	Alignment of visually defined X-ray fields and contrast of light defined X-ray field.

The software VF10 controls solid state X-ray imagers (SSXI) that are similar in performance to the predicates. Performance data are provided according to the "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, issued on: September 1, 2016."

10. Summary of Clinical Tests:

For the subject of this premarket submission, Siemens did not do an evaluation of the clinical image quality as X-ray technology; geometry and SSXI changes are minor.

11. 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 devices are 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:

The MOBILETT Elara Max with VF10 software has the same intended use as the predicate device. The operating environment is the same and the technology differences do not affect safety and effectiveness. Siemens concludes via the documentation provided in this 510(k) submission that the radiology device MOBILETT Elara Max with VF10 is substantially equivalent to the predicate device Mobilett Mira.

13. Guidance documents

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

- 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 Electromganetic Compatibility (EMC) of Electrically-Powered Medical Devices
  Guidance for Industry and Food and Drug Administration Staff Document issued on July 11, 2016. Draft document issued on November 2, 2015.
- 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
- Guidance for Industry and FDA Staff
  Recognition and Use of Consensus Standards
  Document issued on: September 17, 2007
- 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
- Radio Frequency Wireless Technology in Medical Devices
  Guidance for Industry and Food and Drug Administration Staff
  Document issued on: August 14, 2013