Siemens Medical Solutions USA, Inc.
% M. Alaine Medio, RAC
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE TN 37932

July 22, 2020

Re: K193277
Trade/Device Name: SOMATOM On.site and On.scene
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: July 2, 2020
Received: July 6, 2020

Dear M. Alaine Medio:

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)*
K193277

Device Name
SOMATOM On.site and On.scene

Indications for Use *(Describe)*
This computed tomography system is intended to generate and process cross-sectional images by computer reconstruction of x-ray transmission data within a 25 cm field-of-view, primarily for the head and neck.

The images delivered by SOMATOM On.site and On.scene can be used by a trained physician as an aid in diagnosis.

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 – K193277

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Importer / Distributor:	Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard Malvern, PA 19355 Establishment Registration Number: 2240869
Manufacturer:	Siemens Healthcare GmbH Siemensstraße 1 D-91301 Forccheim, Germany Establishment Registration Number: 3004977335
Submitter / Contact Person:	M. Alaine Medio, RAC Regulatory Affairs Professional Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37932 alaine.medio@siemens-healthineers.com
Telephone Number:	(865)206-0337
Fax Number:	(865)218-3019
Alternative Contact:	Tabitha Estes Regulatory Affairs Professional
Date of Submission:	July 2, 2020

Identification of the product

Device Proprietary Name:	SOMATOM On.site and On.scene
Common Name:	Computed Tomography (CT) System
Classification Name:	Computed Tomography X-Ray System per 21 CFR 892.1750
Product Code:	JAK
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Primary Predicate:

Device Proprietary Name:	CereTom
Manufacturer:	Samsung NeuroLogica
Product Code:	JAK
Device Class:	Class II
510(k) Number:	K051765

Predicate Devices:

Device Proprietary Name:	SOMATOM go.Up
Manufacturer:	Siemens Healthcare GmbH
Product Code:	JAK
Device Class:	Class II
510(k) Number:	K192061

Device Proprietary Name:	Mobilett Mira
Manufacturer:	Siemens Healthcare GmbH
Product Code:	IZL
Device Class:	Class II
510(k) Number:	K111912

Recall Information: All applicable recalls are considered and addressed as part of the design control process

Device Description

The Siemens SOMATOM On scanners are comprised of a Computed Tomography (CT) Scanner System (SOMATOM On.scene) which can be mounted on an optional motorized base (SOMATOM On.site). The CT scanner features one continuously rotating tube-detector system that functions according to the fan beam principle. The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The SOMATOM On scanners produce CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens and other vendors as an aid in diagnosis and treatment preparation. The computer system included in the CT Scanner is able to run optional post processing applications.

The software version for the SOMATOM On scanner system is Somaris/10 syngo CT VA35A, is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The software platform SOMARIS/10 syngo CT VA35A is

designed to provide a plugin interface to integrate potential advanced post processing tasks, tools, or extendable functionalities.

As with the primary predicate device, the SOMATOM On. Scanners will be available in a 32 row, 32 slice configuration.

Indications for Use

This computed tomography system is intended to generate and process cross-sectional images by computer reconstruction of x-ray transmission data within a 25cm field-of-view, primarily for the head and neck.

The images delivered by SOMATOM On.site and On.scene can be used by a trained physician as an aid in diagnosis.

Comparison of Technological Characteristics with the Predicate Device
The SOMATOM On.site and On.scene scanners provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software and hardware components of this scanner have been modified or improved in comparison to the predicate devices to support enhanced device functionality and to reduce the potential for scattered radiation.

The SOMATOM On Scanners are similar to the CereTom mobile CT scanner (Neurologica, K051765) which is the primary predicate, and the Go.Platform CT scanners (Siemens K192061). Different features of the two systems are incorporated into the SOMATOM On platform:

- CereTom mobile CT Scanner (Neurologica K051765) – Primary predicate
  Similar to the SOMATOM On scanners that are the subject of this application, the CereTom CT scanner is a mobile scanner with a similar bore size that is used in the same manner as to the SOMATOM On scanners.

- SOMATOM Go. Platform Scanners (Siemens K192061) – Predicate
  Siemens is incorporating multiple features of the Siemens SOMATOM Go scanners into the SOMATOM On platform, including the software that runs the CT Systems, as well as the Gantry rotation mechanics and tablet based touch screen.

The intended use and fundamental scientific technology for the SOMATOM On. remains unchanged from the predicate devices.

The hardware components of the subject device have been modified as compared to the predicate devices to include:

- a gantry translation system
- a Control Device (Scan&GO) user interface (e.g. user interface via mobile tablet software application),
- modified gantry mechanics, and
- an optional motorized base.

- Hybrid air / water X-Ray tube cooling system
- 3kW maximum power Generator
- Gantry mounts at stretcher height in mobile stroke unit
- Method for “complete-angle” shielding of scattered x-ray radiation
- Pre-aligned patient holder attached to scanner system (to reduce human-error in patient alignment resulting in poor scan quality)
- Telescopic gantry design to provide no movement of patient vs scanner during the scan sequence.

The software is based on the commercially available SOMARIS/10 syngo CT VA30A software (K192061). The syngo CT VA35A software supports features that are designed to adapt to a mobile workflow and accommodate the scanner specific hardware/reconstruction.

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Siemens believes that the subject device is substantially equivalent to the predicate devices. Testing and validation have been provided. Test results show that the subject device, the SOMATOM On., is comparable to the predicate devices in terms of technological characteristics and safety and effectiveness, and therefore are substantially equivalent to the predicate devices.

Testing provided and described below support marketing claims associated with the following:

- Point of care imaging benefits, including reducing in-house transports of ICU patients, faster access to neuro CT imaging for immobile patients,
- Telescopic gantry design benefits for scatter radiation reduction
- Radiation safety and protection, including enabling “apron free scanning” when used with both radiation shields employed
- Image quality, including low image noise and quality consistent with SOMATOM CT scanners
- Streamline of the workflow and allowing physicians to determine appropriate facility for transfer when used in ambulatory situations
- Usability claims, including those associated with the Graphical User Interface, patient positioning, single operator system handling and reduction of physical burden on staff associated with patient transport.
- Improved workflow in ICU as well as radiation department

Performance Data

Non-Clinical Testing

Non-clinical testing (integration and functional) including phantom tests and volunteer human scans were conducted for the SOMATOM On. during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. Siemens claims conformance to the following performance standards: ISO 14791, NEMA XR-29, IEC 61223-2-6, IEC 61223-3-5, IEC 62304, NEMA XR-25, and DICOM 3.1-3.20.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the SOMATOM On. scanners in accordance with the following standards: IEC 60601-1, 60601-2-44, and 60601-1-2 (class A).

Radiation safety testing was performed in two configurations – with and without the front protection curtains in use. Both configurations indicate that the radiation is under published limits, and the protection curtain in place reduces the radiation significantly.

Usability testing was performed with both scanner configurations, On.site and On.scene. This testing included formative and Summative evaluations. No new use errors, hazards or hazardous situations were identified. There were not any impacts to the existing residual risks identified.

Verification and Validation

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. The Risk Analysis was completed, and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation supports the claims of substantial equivalence.

Siemens Healthcare conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission.

Additionally, Siemens conforms to the requirements for Radio Frequency Wireless Technology as defined in FDA guidance document "Radio Frequency Wireless Technology in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued on August 14, 2013" by adhering to the EMC and risk based verification and validation requirements in design, testing, and labeling of the wireless remote control components of the subject devices.

Imaging Studies

Phantom scans were performed with phantoms representing adult heads, pediatric bodies and pediatric heads. Additionally, volunteer scans were performed including brain scans with and without contrast, ankle and hand scans. All imaging results were as expected and were determined by a board-certified radiologist to be of high diagnostic quality.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related Risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

Standard	Version	Content	FDA Recognition Number
ES60601-1	:2005 + A1:2012	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	19-4
IEC 60601-1-2	:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances – Requirements And Tests	19-8
IEC 60601-1-3	:2013	Collateral standard: Radiation protection in diagnostic X-ray equipment	12-269
IEC 60601-1-6	:2010 +A1:2013	Collateral Standard: Usability	5-89
IEC 60601-2-28	:2017	Particular measurements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnostics.	12-309
IEC 60601-2-44	:2009 +A1:2012 +A2:2-16	Medical Electrical Equipment - Part 2-44: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Computed Tomography	12-302
IEC 62366-1	:2015	Medical devices -- Application of usability engineering to medical devices	5-114
IEC 61223-2-6	:2006	Constancy Tests – Imaging performance of computed tomography X-ray equipment	12-226
IEC 61223-3-5	:2004	Acceptance Tests – Imaging performance of computer tomography X-ray equipment	12-270
IEC 60825-1	:2007	Safety of Laser Products – Part 1: Equipment Classification and Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]	12-273
NEMA Standard PS3.1-3.20	:2016	Digital Imaging and Communications in Medicine (DICOM)	12-300
NEMA XR-25	:2010	Computed Tomography Dose Check	12-225
NEMA XR-28	:2013	Supplemental Requirements for User Information and System Function related to Dose in CT	12-287
IEC 62304	:2006+A1:2015	Medical Device Software - Software Life Cycle Processes	13-79
ISO 14971	:2007	Application of Risk Management to Medical Devices	5-40

Summary

The features described in this premarket notification are supported with verification and validation testing, dosimetry and imaging performance, and analysis of phantom images to assess device and feature performance during product development. The risk analysis was completed, and risk control implemented to mitigate identified hazards. The test results show that all the software specifications have met the acceptance criteria. Verification and validation testing of the device was found acceptable to support the claim of substantial equivalence.

Conclusions

The predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. The subject device is also tested using the same methods as used for the predicate devices. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrates that the SOMATOM On. Scanners should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM On.site and SOMATOM On.scene scanners perform comparably to the predicate devices currently marketed for the same intended use. Since both devices were tested using the same methods, Siemens believes that the data generated supports a finding of substantial equivalence.