February 18, 2022

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

Re: K212212
Trade/Device Name: Multitom Rax with True2scale Body Scan Option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: January 13, 2022
Received: January 14, 2022

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. 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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
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)*
K212212

Device Name
Multitom Rax with True2scale Body Scan Option

Indications for Use *(Describe)*
Multitom Rax is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be used on pediatric, adult, and bariatric patients. The Multitom Rax is not for mammography examinations.

The True2scale Body Scan functionality (ie., slot-scanning-based acquisition and reconstruction technique) of the Multitom Rax is intended to be used for the generation of a geometrically accurate (in scanning direction) 2-D representation of the spine, the lower limbs or the full body which may be used for the assessment of body axes and skeletal alignment. The True2scale Body Scan feature is not intended to be used for interventional purposes.

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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K212212

510(k) Summary: Multitom Rax with True2scale Body Scan Option

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

Date Prepared: January 10, 2022

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:

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3. Device Name and Classification :

Trade Name:	Multitom Rax with True2Scale Body Scan Option
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	II
Product Code:	OWB
Secondary Product Code:	JAA

4. Legally Marketed Predicate Device:

Trade Name	**SONIALVISION G4 by SHIMADZU corporation**
510(k) Number	K190373
Device Classification Name	Image-intensified fluoroscopic X-ray system
Regulation Number	892.1650
Review Panel	Radiology
Product Code	JAA
Device Class	2

5. Device Description:

The Multitom Rax is a stationary X-ray system for radiography and fluoroscopy. The Multitom Rax consists of a floor mounted patient table (option) and ceiling suspended X-ray tube and a ceiling suspended Solid State X-ray Imager (SSXI). Together with an X-ray generator and a digital imaging system, the Multitom Rax provides comprehensive image acquisition modes to support radiographic and fluoroscopic imaging procedures. X-ray tube and SSXI suspension movements are synchronized to provide rotation around a center. Series imaging acquired during the rotation are provided to 3D post-processing workstations.

With the new True2scale Body Scan technology, the Multitom Rax performs a continuous scan that moves along the patient's vertical axis with a highly collimated radiation beam along a line trajectory using the system's two telescopic arms. The projections, which are acquired during the scanning process, form the basis for a reconstruction to obtain a 2D representation of the scanned object.

6. Indication for Use:

Multitom Rax is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency

applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be used on pediatric, adult, and bariatric patients. The Multitom Rax is not for mammography examinations.

The True2scale Body Scan functionality (i.e., slot-scanning-based acquisition and reconstruction technique) of the Multitom Rax is intended to be used for the generation of a geometrically accurate (in scanning direction) 2-D representation of the spine, the lower limbs or the full body which may be used for the assessment of body axes and skeletal alignment. The True2scale Body Scan is not intended to be used for interventional purposes.

7. Substantial Equivalence:

The new feature True2scale Body Scan adds a term to the indication for use that is similar to the one of the predicate.

The device remains within the same classification regulation for the same technology 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.

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

The subject device with the new software VF11 uses the same X-ray scanning technology as the predicate device. There are substantial differences in the mechanical design of the subject device as compared to the predicate device design. Additional testing was conducted to provide evidence for the robustness of the subject device. Tomosynthetic reconstruction provides a similar image result and there are similarities in the patient environment and the type of user interface.

The following table compares the main performance data of the subject device with the predicate device to substantiate equivalence of the subject device and predicate device.

Comparison of the Subject Device (Multitom Rax with True2scale Body Scan) to Predicate Device (SONIALVISION G4 by SHIMADZU corporation)

Feature	**Predicate device** **SONIALVISION G4 (K190373) by SHIMADZU corporation**	**Subject device** **Multitom Rax with** True2scale Body Scan	**Comment**
Regulation Description	Image-intensified fluoroscopic X-ray system	Image-intensified fluoroscopic X-ray system	Same

Regulation Number	892.1650	892.1650	Same
Classification Product Code	JAA	OWB	The predicate device is not for inter-ventional use therefore it only has the JAA procode
Subsequent Product Code	N/A	JAA	
Indications for use for the Slot technology only	The equipment is intended to be used for the fluoroscopy/ radiography diagnosis in hospital. The equipment must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualificat-ions. The equipment is used for total patient population. The equipment is NOT intended to be used for Mammography screening. The equipment is NOT intended to be used for interventional procedure. The equipment is used for radiographic, fluoroscopic, angiographic and pediatric examinations. Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server. **The Tomosynthesis option for the SONIALVISION G4 is intended to generate tomographic images of human anatomy**	Multitom Rax is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be used on pediatric, adult, and bariatric patients. The True2scale Body Scan feature employs a slot-scanning-based acquisition and reconstruction technique to produce a 2D representation of the scanned object which is intended for the assessment of body axes and skeletal alignment. The True2scale Body Scan feature itself is not intended	The subject device has a broader range of applications. The tomosynthesis feature and the subject of this application is similar to the predicate

	including chest or extremities. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition. The device is not intended for mammographic applications	to be used for interventional purposes.	
Mechanical System design	Remotely controlled Fluoroscopy Table	Twin robotic arms suspended from ceiling with floor-mounted table, remotely controlled	Different design requires additional tests for mechanical integrity
X-ray beam geometry	Slot technology	Slot technology	Same
High voltage generator	80 kW	65 kW or 80 kW	Similar
X-Ray Tube	Max anode heat capacity 750 kHU Focal size: 0.7 / 1.2 mm	Max anode heat capacity 820 kHU Focal size: 0.6 / 1.0 mm	Similar
Slot imaging coverage	Max.141cm × 42cm	Max.170cm × 43cm	Similar
X-ray detector	Solid State X-ray Imager	Solid State X-ray Imager	Same
Image processing	Image reconstruction with tomosynthesis	Image reconstruction with tomosynthesis	Same
Image geometry	True 1:1 in scan direction	True 1:1 in scan direction	Same
Slot width	40 mm in HS mode 40 mm in HQ mode	50 mm	Similar

9. Summary of Non-Clinical Tests:

The software VF11 design was completed in accordance with Siemens Quality Management System Design Controls and verification and validation testing were successfully conducted. The following performance tests were conducted:

- Testing was conducted with a metal ruler to present the linear movement of the system and the robustness for the intended application

- X-ray exposure dose evaluations provide evidence of the low dose claim when compared to current technologies with tube tilt and image stitching.

10. Summary of Tests to comply with International Standards

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

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 2014 Ed 4.0	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 2015 Ed 1.0	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 2016	Digital Imaging and Communications in Medicine (DICOM) Set

IEC 60601-2-43: 2017	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
ISO EN ISO 15223-1 2017-04	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62220-1-1:2015	Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging

11. Summary of Clinical Tests:

For the subject of this premarket submission, Siemens did an evaluation of the clinical image quality as the True2scale Body Scan technology is new.
The purpose of this clinical image evaluation was to show that even though the two orthogonal views (a.p. & lateral) are acquired sequentially, the resulting images are correlating sufficiently to allow a detection and evaluation of the vertebral alignment in each projection plane.
The evaluation of ten (10) anonymized clinical image sets by expert, board-certified radiologists has shown that all image sets were found to be of acceptable clinical image quality.

12. 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 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 health care 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.

13. Conclusion as to Substantial Equivalence:

The Multitom Rax with the True2scale Body Scan feature is intended for similar indications for use as the predicate device. There are substantial differences in the mechanical design of the subject device as compared to the predicate device design. Additional testing was conducted to provide evidence for the robustness of the subject device. The operating environment is the same and the technology similar. Siemens concludes via the documentation provided in this 510(k) submission that the True2scale Body Scan feature of the Multitom Rax is substantially equivalent to the predicate device SONIALVISION G4.

14. Guidance documents

The following FDA guidance documents were utilized in 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 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 Medical Devices - 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