



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Mr. Darren Dorman
Regulatory Affairs Specialist
40 Liberty Blvd., 65-1A
MALVERN PA 19355

November 13, 2015

Re: K152928
Trade/Device Name: Multitom Rax
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Codes: OWB, JAA
Dated: October 5, 2015
Received: October 6, 2015

Dear Mr. Dorman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a slight shadow effect behind the letters.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152928

Device Name
Multitom Rax

Indications for Use (Describe)

The Multitom Rax is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

The Multitom Rax is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The unit may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiography, digital angiography and digital subtraction angiography (DSA).

The Multitom Rax may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

The Multitom Rax is not 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.

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510(k) Summary: Multitom Rax

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

Date Prepared: October 2, 2015

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

Manufacturing Site:

SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany

Establishment Registration Number:
3004977335

2. Contact Person:

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Email : patricia.d.jones@siemens.com

3. Device Name and Classification:

Trade Name: Multitom Rax
Device: Interventional fluoroscopic X-ray system
Regulation Description: Image-intensified fluoroscopic x-ray system
Regulation Medical Specialty: Radiology
Review Panel: Radiology
Product Code: OWB
Subsequent Product Code: JAA
Submission Type: Traditional 510(k)
Regulation Number: 892.1650
Device Class 2

4. Legally Marketed Predicate Devices:

Primary Predicate:
Trade Name: AXIOM Luminos dRF
510(k) Number: K062623
Device: Interventional Fluoro X-Ray System
Regulation Description: Image-intensified fluoro X-ray System
Regulation Medical Specialty: Radiology
Review Panel: Radiology
Product Code: OWB
Subsequent Product Codes: JAA, OXO
Submission Type: Traditional 510(k)
Regulation Number: 892.1650
Device Class 2
Recall Information: Z-0326-2009; Z-0327-2009; Z-0717-2011; Z-1159-2012; Z-1383-2012; Z-1848-2013; Z-0016-2014; Z-1845-2014; Z-0374-2014; Z-0140-2014; Z-1711-2014; Z-2292-2014; Z-2649-2014

Secondary Predicate:
Trade Name: AXIOM Aristos FX Plus
510(k) Number: K061054
Device: Solid State X-Ray Imager
Regulation Description: Image-intensified fluoro X-ray System
Regulation Medical Specialty: Radiology
Review Panel: Radiology
Product Code: MQB
Submission Type: Special 510(k)
Regulation Number: 892.1680
Device Class 2
Recall Information: Z-0984-03; Z-0163-2009; Z-1959-2011; Z-0860-2012; Z-1583-2015

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 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.

6. Indication for Use:

The Multitom Rax is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

The Multitom Rax is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The unit may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiography, digital angiography and digital subtraction angiography (DSA).

The Multitom Rax may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

The Multitom Rax is not for mammography examinations.

7. Substantial Equivalence:

The new device Multitom Rax is within the same classification regulation for the same indication for use as the Primary predicate AXIOM Luminos dRF (K062623, cleared 08/22/2007). The mechanical design is compared to the Secondary predicate the AXIOM Aristos FX Plus (K061054, cleared 05/09/2006). Documentation is provided to support a claim of substantial equivalence to these Siemens' predicate devices.

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

Changes implemented for the subject device include hardware and software changes. The subject device, Multitom Rax, uses the same X-ray generator, the same X-ray tube and the same SSXI with the same digital imaging system and same image processing software as the Primary predicate AXIOM Luminos dRF. The system can be controlled in the room or remotely in the same fashion as the Primary predicate AXIOM Luminos dRF.

The mechanical design concept is the same as for the Secondary predicate the AXIOM Aristos FX Plus.

The subject device was changed in regard to movement flexibility of the suspension arms and increased number of predefined automatic positions of tube and SSXI. Dedicated positions for certain examinations can be stored with the organ programs. When such an organ program is selected the Multitom Rax automatically moves to that position. This feature was also available with the secondary predicate AXIOM Aristos FX Plus.

The software algorithm for this movement has been optimized to find the fastest way to that position. There are hardware and software collision control features in place as well. The scanner offers both automated tube-to-detector and detector-to-tube alignment. This feature is called: "RAXalign." Due to the increase in movement speed and the addition of circular movement a more sophisticated collisions software was implemented.

The automatic exposure control processes the data from 5 dose measurement fields instead of 3 compared with the predicate devices. The number of organ programs was increased and additional programs are provided for pediatric applications.

Summary of Non-Clinical Test Data:

Multitom Rax is a new device based on components used with both predicate devices AXIOM Luminos dRF(K062623) and AXIOM Aristos FX Plus (K061054) The Multitom Rax design was completed in accordance with Siemens Quality Management System Design Controls and Engineering, standards compliance, and Verification and Validation testing were successfully conducted. Tests were performed on the Multitom Rax which demonstrated that the device is safe and effective, performs comparably to the predicate devices, and is substantially equivalent to the predicate devices. Tests included verification/validation testing to internal functional specifications (including software). The Multitom Rax uses the same solid state X-ray imager (SSXI) as the Primary predicate. X-ray geometry and techniques are the same so that clinical image comparisons involving SSXI were not conducted. Documentation provided demonstrates compliance of the new device to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation tests to software requirements and software risk hazards.

Performance testing confirmed that the Multitom Rax complies with 21 CFR 1020.30-32 Federal Performance Standards for X-Ray Fluoroscopic equipment and with relevant voluntary safety standards for Electrical Safety

and Electromagnetic Compatibility testing, specifically IEC standards listed in the table below. Together, the verification/validation activities successfully confirmed device requirements has been fulfilled and that system functionality is consistent with the user needs and intended uses. The Multitom Rax device correctly performs as designed and raises no new questions regarding safety or effectiveness. Therefore, when compared to the predicate devices the Multitom Rax supports a determination of substantial equivalence to the predicate devices.

9. Summary of Non-Clinical Tests

The Siemens Multitom Rax complies with the voluntary standards as listed in the following table:

Development Organization and Reference Number	Title of Standard
IEC 60601-1 3 rd , 2005	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2 3 rd 2007	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: 3 rd 2008	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, 2007	Medical devices – Application of usability engineering to medical devices
ISO 14971, 2010	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 Ed 2.0, 2010	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, 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, 2011	<u>Digital Imaging and Communications in Medicine (DICOM) Set</u>
IEC 60825-1, 2007	Safety of laser products – Part 1: Equipment classification, and requirements

ISO 10993-1, 2009	<u>Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process</u>
IEC 60601-2-43, 2010	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

10 Summary of Clinical Tests:

For the subject of this premarket submission, Siemens did not do an evaluation of the clinical image quality as required by the “Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices.” because the subject device uses the same SSXI as the Primary predicate device.

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 Multitom Rax 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.

12. Conclusion as to Substantial Equivalence:

The Multitom Rax is intended for the same indications for use as the Primary predicate AXIOM Luminos dRF. The operating environment is the same and mechanical design the same as the Secondary predicate the AXIOM Aristos FX Plus. Siemens concludes via the documentation provided in this 510(k) submission that the Multitom Rax is substantially equivalent to the AXIOM Luminos dRF (K051133 cleared 06/01/2005) and the AXIOM Aristos FX Plus (K061045 cleared 05/09/2006).