



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

Siemens Medical Solutions USA, Inc.  
% Ms. Patricia Jones  
Regulatory Affairs Specialist  
51 Valley Stream Parkway, D-02  
MALVERN PA 19355

December 18, 2014

Re: K142049  
Trade/Device Name: Multix Fusion VA30 & VA40  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: KPR  
Dated: November 25, 2014  
Received: November 26, 2014

Dear Ms. Jones:

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 A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, large watermark of the letters "FDA" in a light blue color.

Robert A. Ochs, Ph.D.  
Acting 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)

K142049

Device Name

Multix Fusion

Indications for Use (Describe)

The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position.

The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired), or fixed (integrated) or wireless digital detector for generating diagnostic images by converting x-rays into image signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

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: Multix Fusion X-ray System

**Company:** Siemens Medical Systems, Inc.  
51 Valley Stream Parkway  
Malvern, PA 19355

**Date Prepared:** November 25, 2014

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, Inc.  
51 Valley Stream Parkway, E-50  
Malvern, PA 19355

**Establishment Registration Number:** 2240869

**Location of Manufacturing Site:**

Siemens Shanghai Medical Equipment Ltd.  
278 Zhou Zhu Road, Shanghai  
201318, China

**Establishment Registration Number:** 3003202425

**Establishment Registration Number:** 3004977335

### 2. Contact Person:

Ms. Patricia D Jones  
Technical Specialist, Regulatory Submissions  
Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway D-02  
Malvern, PA 19355  
Phone: (610) 448 -3536 Fax: (610) 448-1787  
Email: patricia.d.jones@siemens.com

### 3. Device Name and Classification:

<b>Trade Name:</b>	Multix Fusion
<b>Classification Name:</b>	Stationary X-Ray System
<b>Classification Panel:</b>	Radiology
<b>Classification Regulation:</b>	21 CFR §892.1680
<b>Device Class:</b>	Class II
<b>Product Code:</b>	90 KPR

### 4. Legally Marketed Predicate Devices

<b>Trade Name:</b>	Multix Fusion
<b>510(k) #:</b>	K121513

**Clearance Date:** August 10, 2012  
**Classification Name:** Stationary X-ray System  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR §892.1680  
**Device Class:** Class II  
**Product Code:** 90 MQB

**Trade Name:** YSIO Max  
**510(k)#:** K133259  
**Clearance Date:** January 24, 2014  
**Classification Name:** Stationary X-ray System  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR§892.1680  
**Device Class:** Class II  
**Product Code:** 90 KPR

**5. Device Description:**

Siemens Medical Solutions USA, Inc. intends to market a Radiography X-ray system the Multix Fusion VA30 and VA40. This 510(k) submission describes several modifications to the previously cleared predicate devices the Multix Fusion K121513 and the YSIO Max Radiography X-ray system K133259. The following Modifications are made to the cleared predicate devices and developed into the Subject Device the Multix Fusion VA 30 and VA40:

**1).** A new 43x43cm fixed detector, Pixium 4343RG manufactured by Trixell; **2).** A new 43x36cm wireless detector, Paxscan 4336W manufactured by Varian. **3).** A new 43x43cm fixed detector, Pixium 4343RC manufactured by Trixell. **4)** Slight change in the Indication for Use Statement as compared to the secondary predicate Ysio Max K133259). **5).** Bucky Wall Stand (BWS) changed from manual to motor driven movement. **6).** Radiographic Grid change from movable 50-line grid to stationary 80-line grid. **7).** A remote control console to control BWS motorized movement, center align, collimator size and collimator light and **8).** An optional Multix DR-Upgrade with wireless detector (Varian Paxscan 4336W) for the predicate the Multix Fusion, K121513 is also available within Multix Fusion VA40.

The Multix Fusion VA30 and VA40 Radiography X-ray system is designed as a modular system of x-ray components (ceiling suspension with X-ray tube, Bucky wall stand, Bucky table, X-ray generator, portable wireless and integrated detectors) which is the same as the predicate the Multix Fusion K121513.

**6. Indication for Use:**

The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient

sitting, standing, or in the prone position.

The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired), or fixed (integrated) or wireless digital detector for generating diagnostic images by converting x-rays into image signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

**7. Substantial Equivalence:**

The Multix Fusion VA 30 and VA40 is substantially equivalent to the commercially available Siemens Multix Fusion cleared 8/10/2012 in K121513; and the YSIO Max, cleared on 01/24/2014 in K133259. See **Table 1**.

**Table 1:** Predicate Device Comparable Properties

Predicate Devices Name & Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Multix Fusion Siemens AG	K121513	8/10/2012	Indication for use X-ray technology Image processing Mechanical design
Ysio MAX Siemens AG	K133259	01/24/2014	Indication for use X-ray technology Image processing Mechanical design

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

The Multix Fusion VA30 and VA40 Radiography X-ray system is designed as a modular system of x-ray components (ceiling suspension with X-ray tube, Bucky wall stand, Bucky table, X-ray generator, portable wireless and integrated detectors) same as the predicate Multix Fusion. The Multix Fusion VA30 and VA40 is comparable in indication for use, design, material, functionality, technology, energy source and is considered substantially equivalent to the commercially available Siemens’ Ysio Max and the Multix Fusion. It uses the same or similar components cleared in the Multix Fusion and Ysio Max (e.g. tube, generator, ceiling-mounted tube support, table, Bucky wall stand and imaging system).

The components of the subject device have many of the same technological characteristics as the ones from the predicate devices. There are several technological characteristics that differ slightly as shown in the comparison tables (indicated as “similar”).

Testing and validation is completed. Test results shows that the subject device the Multix Fusion VA30 and VA40 with all its components are comparable to the predicate devices and therefore is substantial equivalent to its predicate devices.

The subject device the Multix Fusion VA30 and VA40 does not affect the intended use of the device nor does it alter its fundamental scientific technology from the 510(k) cleared predicate devices the Multix Fusion and the Ysio Max.

## 9. **Nonclinical Performance Testing**

Non-clinical tests were conducted for the Multix Fusion VA30 and VA40 during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

a signed statement of conformance to the following eleven (11) performance standards: **60601-1 3<sup>rd</sup>**; **60601-1-2 3<sup>rd</sup> 2007**; **60601-1-3: 2<sup>nd</sup> 2008**; **62366: 2007**; **14971:2010**; **62304 Ed. 1.0 2006**; **60601-2-28 Edition 2.0 (2010)**; **60601-2-54 2009**; **PS 3.1 - 3.20 (2011)** **60601-1-6** and **10993-1:2009**.

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. Non-clinical tests (integration and functional) were conducted on the Multix Fusion VA30 and VA40 during product development.

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

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

Clinical testing is not applicable due to the fact that no new clinical applications were introduced to the system.

## 10. **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 Multix Fusion VA30 and VA40 Radiography X-ray system is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Risk management is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled via software

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

**11. Conclusion as to Substantial Equivalence:**

The Multix Fusion VA30 and VA40 is intended for a similar indication for use as the predicate Multix Fusion and the predicate YSIO Max. The operating environment and mechanical design is similar. It is Siemens opinion, that the Multix Fusion VA30 and VA40 is substantially equivalent to the Multix Fusion, cleared 8/10/2012 in K121513; and the YSIO Max, cleared 01/24/2014 in K133259 x-ray system.

The predicate device was cleared based on non-clinical supportive information. Therefore, the Subject Device non-clinical data supports the safety of software with verification and validation testing. Verification and validation testing demonstrates that the Multix Fusion VA30 and VA40 should perform as intended. The non-clinical test data demonstrate that the Multix Fusion VA30 and VA40 device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens is of the opinion that the Multix Fusion VA30 and VA40 do not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.