510(k) Summary: Multix Select DR X-ray System

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

Date Prepared: March 12, 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 AG
Medical Solutions
X-Ray Products
Hennekstrasse 127
DE-91052 Erlangen
Establishment Registration Number: 3002808157

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

Headquarters:
Siemens AG
Wittelsbacherplatz 2
D-80333 Munich 2, Germany
Establishment Registration Number: 3003202425

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) 448-3538   Fax: (610) 448-1787

Email: patricia.d.jones@siemens.com
3. Device Name and Classification:
   Trade Name: Multix Select DR
   Classification Name: Stationary X-Ray System
   Classification Panel: Radiology
   Classification Regulation: 21 CFR §892.1680
   Device Class: Class II
   Product Code: 90 KPR

4. Legally Marketed Predicate Device
   Trade Name: Multix Fusion
   510(k) #: 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 KPR

   Device Description:
   Multix Select DR is a product sharing same image system platform with Siemens' Multix Fusion x-ray system cleared under Premarket Notification K121513 on 08/10/2012, but target to low end DR market segment. The Multix Select DR system consists of radiologic table, x-ray generator, x-ray tube, flat panel detector (mobile (wired)), imaging system and Bucky-wall stand.

   The Multix Select DR offers the following system configurations:
   - A digital radiography system with a mobile (wired) flat panel detector;

   The key components are a Patient Table and a Bucky wall stand which are available in different configurations. The x-ray tube is a Single Tank Tube Assembly and mounted in a column integrated on the patient table. A manual movement of the x-ray tube is available.

   Similar to the cleared Multix Fusion x-ray system, Multix Select DR has the same or similar comparable components. It does not affect the indication for use nor the intended use of the device nor does it alter its fundamental scientific technology.

5. Indication for Use:
   The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR -systems, and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.
6. **Substantial Equivalence:**
The Multix Select DR is substantially equivalent to the commercially available Siemens Multix Fusion (K121513) radiographic x-ray system with similar indication for use. The Multix Fusion was described in premarket notification K121513 which received FDA Clearance on August 10, 2013. (See Table 1 below).

<table>
<thead>
<tr>
<th>Predicate Device Name &amp; Manufacturer</th>
<th>510(k) Number</th>
<th>Clearance Date</th>
<th>Comparable Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multix Fusion SSME</td>
<td>K121513</td>
<td>08/10/2012</td>
<td>Indications for use</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>X-ray tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Collimator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Table</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>X-ray Generator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bucky Wall stand</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Digital Imaging system</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flat panel detector</td>
</tr>
</tbody>
</table>

7. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The Multix Select DR uses the same Digital Imaging system as the predicate device. The differences in the Subject Device, such as Generator, X-ray Tube, Collimator, radiological table and Bucky Wall Stand, do not affect the safety or effectiveness of the device. The Multix Select DR uses a flat panel detector similar to the predicate device, the difference does not affect the safety or effectiveness, which is supported by conforming to detector characteristics described per the FDA Guidance for Submission of 510(k)'s for Solid State X-ray Imaging Devices, (issued on Augus 6, 1999).

Table 2: Subject and Predicate Device Technical Properties

<table>
<thead>
<tr>
<th>Comparable Properties</th>
<th>Subject Device Multix Select DR</th>
<th>Predicate Device Multix Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR-systems, and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.</td>
<td>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...</td>
</tr>
</tbody>
</table>
Multix Select DR 510(k) K132934 AI Response

<table>
<thead>
<tr>
<th>Comparable Properties</th>
<th>Subject Device Multix Select DR</th>
<th>Predicate Device Multix Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray tube</td>
<td>OPTIPHOS 135/30/55R</td>
<td>OPTITOP 150/40/80HC-100</td>
</tr>
<tr>
<td>Collimator</td>
<td>Manual</td>
<td>Manual or automatic* (ACSS)</td>
</tr>
<tr>
<td>Table</td>
<td>Floating table top</td>
<td>Lifting and floating table top</td>
</tr>
<tr>
<td>X-ray Generator</td>
<td>55 kW</td>
<td>55 kW 85 kW 80 kW</td>
</tr>
<tr>
<td>Digital Imaging system</td>
<td>Fluorospot Compact High - Res Digital Imaging</td>
<td>Fluorospot Compact High - Res Digital Imaging</td>
</tr>
<tr>
<td>Flat panel detector</td>
<td>DRZ+ (Gadox) with amorphous silicon (a-Si) technology</td>
<td>Cesium iodide scintillator (CaI) with amorphous silicon (a-Si) technology</td>
</tr>
</tbody>
</table>

The modifications included in the comparison table above (see Table 2) and described throughout this submission do not alter the Indications for use or fundamental scientific technology of the legally marketed predicate device. The differences between the legally marketed predicate device and the subject device have been assessed via Verification and Validation as well as Risk Management. Any differences in technological characteristics are accompanied by information within this submission that demonstrates the device is as safe and effective as the predicate device and do not raise different questions of safety and effectiveness than the predicate.

8. Performance Testing
Siemens claims conformance to a signed statements of performance standards and Federal X-ray Performance Standards. This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software 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.

Detector of the Subject Device conforms to the guidance for the submission of 510(k) for Solid State X-ray Imaging Devices. Non-clinical Data is provided in Original 510k submission Appendix G.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.
EMC Mechanical Safety electrical safety was evaluated according to the IEC Standards. Siemens certify to conformance Voluntary Standards Covering Electrical and Mechanical Safety.” (See Table 3 below). In conclusion, the identified risk of EMC/Mechanical/Electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness.

Siemens conforms to Voluntary and EPCR standard (see Table 3 below). Siemens hereby certifies that the subject device the Multix Select DR will be in compliance with the following recognized consensus standards covering electrical and mechanical safety listed in Table 3 below.

Table 3: Conformance to Voluntary Standards

<table>
<thead>
<tr>
<th>Recognition Number</th>
<th>Product Area</th>
<th>Title of Standard</th>
<th>Refer. No. &amp; Date</th>
<th>Standards Dev. Org.</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-4</td>
<td>General</td>
<td>Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995</td>
<td>60601-1</td>
<td>IEC</td>
</tr>
<tr>
<td>5-40</td>
<td>General</td>
<td>Medical devices - application of risk management to medical devices</td>
<td>14971 Second edition 2007</td>
<td>ISO</td>
</tr>
</tbody>
</table>
 Siemens hereby certifies that the subject device the Multix Select DR will meet the applicable requirements of the FDA Performance Standards for Ionizing Radiation Emitting Products for diagnostic X-Ray systems and their major components, as listed below, prior to introduction into interstate commerce. All data will be available for inspection at the firm.

### Table 3 (cont.): Required Performance Standards

<table>
<thead>
<tr>
<th>21 CFR Title No.</th>
<th>Title of 21 CFR Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1020.30(c)</td>
<td>Manufacturer's Responsibility (Certification)</td>
</tr>
<tr>
<td>1020.30(e)</td>
<td>Identification of X-ray components</td>
</tr>
<tr>
<td>1020.30(g)</td>
<td>Information to be provided to assemblers</td>
</tr>
<tr>
<td>1020.30(h)</td>
<td>Information to be provided to users</td>
</tr>
</tbody>
</table>
9. **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 Select DR 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 evaluating and post processing of 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.

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

The Multix Select DR is intended for the same clinical use as Multix Fusion, and it uses the same or similar components as cleared in Multix Fusion.

The functionality of Multix Select DR is similar to the predicate device. It is Siemens opinion, that the Multix Select DR is substantially equivalent to the cleared predicate device the Multix Fusion (K121513) radiographic x-ray system.
April 10, 2014

Siemens Medical Solutions, Inc.
% Ms. Patricia Jones
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway
MALVERN PA 19355

Re: K132934
Trade/Device Name: Multix Select DR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: March 12, 2014
Received: March 13, 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

[Signature]

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
## Indications for Use

The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR-systems and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.

## Type of Use (Select one or both, as applicable)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 70 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@hhs.gov

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**Siemens**

Multix Select DR 510(k) K132934 AI Response

<table>
<thead>
<tr>
<th>DEPARTMENT OF HEALTH AND HUMAN SERVICES</th>
<th>Form Approved: OMB No 0910-0120</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Administration</td>
<td>Expiration Date: January 31, 2017</td>
</tr>
<tr>
<td>Indications for Use</td>
<td></td>
</tr>
</tbody>
</table>

**S10(k) Number (if known)**

K132934

**Device Name**

Multix Select DR

**Indications for Use (Describe)**

The Multix Select DR is a digital system used for making X-ray exposures of the head, spinal column, abdomen, thorax (lungs), internal organs and extremities with/without using conventional film/screen and CR-systems and may be used on pediatric, adult and bariatric patients. The Multix Select DR system is not meant for mammography.