510(k) SUMMARY
FOR
SOMATOM Perspective

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: March 11, 2014

This summary of 510(k) 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.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD.
278 Zhou Zhu Rd
Shanghai, China 201318

Establishment Registration Number:
3003202425

2. Contact Person:
Mrs. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-1772 Fax: (610) 448-1778
Email: kimberly.mangum@siemens.com

3. Device Name and Classification
Product Name: SOMATOM Perspective
Proprietary Trade Name: SOMATOM Perspective
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
4. Substantial Equivalence:
Siemens SOMATOM Perspective 16 and 32 slice configurations are substantially equivalent to the following medical devices in commercial distribution:

<table>
<thead>
<tr>
<th>Predicate Device Name</th>
<th>FDA Clearance Number</th>
<th>FDA Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOMATOM Perspective</td>
<td>K113287</td>
<td>May 23, 2012</td>
</tr>
<tr>
<td>SOMATOM Emotion 16</td>
<td>K050297</td>
<td>March 01, 2005</td>
</tr>
</tbody>
</table>

5. Device Description:
The SOMATOM Perspective 16 and 32 slice configurations are whole body X-ray Computed Tomography Systems. The SOMATOM Perspective 16 and 32 slice configurations produce CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

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 new version of system software, syngo®
SIEMENS

CT VC28 (SOMARIS/5 VC28) supports several new features which support more economical and energy efficient scanner operation.

6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:
The SOMATOM Perspective 16 and 32 slice configurations are comparable in Indications for Use, material, functionality, technology, energy source, and are considered substantially equivalent to the predicate devices SOMATOM Perspective (K113287, clearance date May 23, 2012) and the SOMATOM Emotion 16 (K050297, clearance date March 01, 2005).

The SOMATOM Perspective 16 and 32 slice configurations are intended to produce whole body cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The imaging components (tube, collimator, detector, and DAS) are the same as the predicate devices.

The SOMATOM Perspective 16 and 32 slice configurations include the following new system features designed to allow more efficient system use:

- **eCockpit** - Software bundle designed to support more efficient system use
- **eStart** – Software option designed to extend the tube life by pre-warming the tube before a scan
- **eSleep** – Software option designed to save energy by stopping the gantry rotation during scan breaks

Additionally, the SOMATOM Perspective 16 and 32 slice configurations support the following acquisition method:

- **Single Source Dual Energy Acquisition** – Scanning and reconstruction of two spiral scans with different tube voltages (Dual Energy)

The intended use and fundamental scientific technology are similar to the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.
7. Nonclinical Testing: The SOMATOM Perspective 16 and 32 slice configurations are designed to fulfill the requirements of following standards:

<table>
<thead>
<tr>
<th>Recognition Number</th>
<th>Product Area</th>
<th>Title of Standard</th>
<th>Reference Number and Date</th>
<th>Publication Date</th>
<th>Standards Development Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-40</td>
<td>General</td>
<td>Medical devices – Application of risk management to medical devices</td>
<td>14971 Second Edition 2007-03-01</td>
<td>08/20/2012</td>
<td>ISO</td>
</tr>
<tr>
<td>13-8</td>
<td>Software</td>
<td>Medical device software – Software life cycle processes</td>
<td>62304 First edition 2006-05</td>
<td>08/20/2012</td>
<td>IEC</td>
</tr>
<tr>
<td>12-225</td>
<td>Radiology</td>
<td>Computed Tomography Dose Check</td>
<td>XR-25</td>
<td>03/18/2011</td>
<td>NEMA</td>
</tr>
</tbody>
</table>
This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) and phantom testing were conducted for the SOMATOM Perspective 16 and 32 slice configurations during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

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 of the device was found acceptable to support the claims of substantial equivalence.

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.

EMC/electrical safety was evaluated according to the IEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of 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.

8. Indications for Use:
The Siemens SOMATOM Perspective system is intended to produce cross sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Perspective is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images.

For cardiac imaging, which is an option on the system, a new reconstruction algorithm (iTRIM - Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

The images and results delivered by the SOMATOM Perspective can be used by a trained physician as an aid in diagnosis.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)
9. **General Safety and Effectiveness Concerns:**
   The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

   Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. **Conclusion as to Substantial Equivalence**
    In summary, Siemens is of the opinion that the SOMATOM Perspective 16 and 32 slice configurations do not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.
April 30, 2014

Siemens Medical Solutions USA, Inc.  
Kimberly Mangum  
51 Valley Stream Pkwy.  
MALVERN PA 19355  

Re: K133590/S002
   Trade/Device Name: SOMATOM Perspective  
   Regulation Number: 21 CFR 892.1750  
   Regulation Name: System, X-Ray, Tomography, Computed  
   Regulatory Class: II  
   Product Code: JAK  
   Dated: March 25, 2014  
   Received: March 31, 2014  

Dear Ms. Mangum:

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

Sincerely yours.

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

Enclosure
510(k) Number (if known)
K133590

Device Name
SOMATOM Perspective

Indications for Use (Describe)

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