### Section 5
510(k) Summary

**Submitter:** Siemens Medical Solutions USA, Inc. Oncology Care Systems  
4040 Nelson Avenue  
Concord, CA 94520  

**Contact:** Christine Dunbar  
Senior Regulatory Affairs Specialist  

**Phone:** (925) 602-8139  
**Fax:** (925) 602-8008  
**Email:** christine.dunbar.ext@siemens.com  

**Proprietary Name:** PreScision™ Option  
**Common Name:** An accessory to: Accelerator, Linear, Medical  
**Classification:** 892.5050  
**Product Code:** IYE  

**Substantial Equivalence Claimed To:**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Clearance</th>
<th>Claim of Equivalence For:</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIEMENS ARTISTE™</td>
<td>K072485</td>
<td>The Stereo mode with the 160 MLC</td>
</tr>
<tr>
<td>SIEMENS ONCOR™</td>
<td>K060226</td>
<td>ONCOR™ and PRIMUS™ linear accelerator families with Stereo Mode and COHERENCE Workspaces (or the re-branded syngo® Suite for Oncology Workspaces) and the 82 leaf MLC marketed as OPTIFOCUS.</td>
</tr>
<tr>
<td>SIEMENS PRIMUS™</td>
<td>K993425</td>
<td>PRIMUS™ family of linear accelerators with the Stereo Mode, PRIMEVIEW 3i system, the 58 leaf MLC</td>
</tr>
<tr>
<td>Varian Trilogy™</td>
<td>K061140</td>
<td>Stereotactic (SRT) and Stereotactic Radio-Surgery (SRS) Radiation Therapy with high dose beam rate.</td>
</tr>
<tr>
<td>TomoTherapy Hi-Art™</td>
<td>K060912</td>
<td>Stereotactic (SRT) and Stereotactic Radio-Surgery (SRS) with unflattened beam delivery and extended treatment field for Stereotactic Body Radiation Therapy.</td>
</tr>
<tr>
<td>Accuray Cyberknife™</td>
<td>K052325</td>
<td>Stereotactic (SRT) and Stereotactic Radio-Surgery (SRS) robotic delivery system and increased dose rates for reduced treatment times.</td>
</tr>
</tbody>
</table>

The ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerators with the PreScision™ Option as described in this premarket notification has similar intended use and fundamental scientific technical characteristics as the devices listed above.

### Description Summary:

510(k) for PreScision™ Option  

CONFIDENTIAL  
.Page Sect. 5/1
Within the submission the following internal naming conventions are used:

<table>
<thead>
<tr>
<th>Market Name</th>
<th>Internal naming convention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARTISTETM</td>
<td>ARTISTETM linear accelerator and ACCEL release 4+</td>
</tr>
<tr>
<td>ONCOR TM Expression</td>
<td>ONCOR TM linear accelerator and ACCEL release 2+</td>
</tr>
<tr>
<td>ONCOR TM Avant-Garde</td>
<td>ONCOR TM linear accelerator and ACCEL release 2+</td>
</tr>
<tr>
<td>PRIMUSTM</td>
<td>PRIMUSTM linear accelerator and ACCEL release 2+</td>
</tr>
<tr>
<td>PRIMEVIEWTM</td>
<td>Siemens proprietary verify and record system. The syngo® based PRIMEVIEW is hosted on the COHERENCE™ Therapist Workspace. The syngo® base version is marketed as PRIMEVIEW 3i and is used on the PRIMUS™ linear accelerator systems.</td>
</tr>
<tr>
<td>COHERENCE™ Therapist Workspace</td>
<td>RTT Workspace contains the SIEMENS proprietary verify and record system as well as access to the Oncology Information System and directly connects to the LINAC control console.</td>
</tr>
<tr>
<td>MVCB</td>
<td>Mega-Voltage Cone Beam – a method of obtaining 3 dimensional data for portal imaging.</td>
</tr>
<tr>
<td>160 MLC™</td>
<td>160-leaf multi-leaf collimator</td>
</tr>
<tr>
<td>OPTIFOCUS™</td>
<td>82-leaf multi-leaf collimator</td>
</tr>
<tr>
<td>OPTIVUE™</td>
<td>aSi flat panel electronic portal imaging device (EPID) AL7 model</td>
</tr>
<tr>
<td>OPTIVUE 1000ST</td>
<td>aSi flat panel electronic portal imaging device (EPID) AG9 model</td>
</tr>
<tr>
<td>syngo® Therapist Workspace, RTT Express™</td>
<td>RTT Workspace contains the SIEMENS proprietary verify and record system as well as access to the Oncology Information System and directly connects to the LINAC control console on the ARTISTETM linear accelerator system.</td>
</tr>
<tr>
<td>syngo® Suite for Oncology Workspaces</td>
<td>Syngo® based workstation, re-branded COHERENCE workspaces.</td>
</tr>
<tr>
<td>syngo®</td>
<td>Siemens proprietary software architecture and hosting SIEMENS software applications organized by task cards on a dedicated workstation.</td>
</tr>
</tbody>
</table>

For further definitions of the terms used in this submission, refer to the Glossary in Section 24.

Technological Characteristics:

The PreScision™ Option:

The PreScision™ Option package is an optional feature to the existing SIEMENS ARTISTETM, ONCOR™ and PRIMUS™ family of medical linear accelerator devices [LINAC]. The basic design, safety features and function of the LINAC remain unchanged. The PreScision feature supports Stereotactic Radiation Therapy (SRT) and Stereotactic Radio-surgery (SRT) using the conventional linear accelerator and subsystems for the delivery of precision high dose X-Ray photon energy for treatment of lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

The PreScision option supports the delivery of up to 2,000 (± 2%) MU / Minute X-Ray photon beam for either single-session radiosurgery or hypo-fractionated stereotactic treatment using a calibrated 6.67 MV photon energy spectrum consisting of an unflattened beam geometry, a selectable field size...
of 5cm x 5 cm up to 40cm x 40 cm, collimated by any validated third party stereotactic accessory such as a stereotactic cone or a Multi-leaf collimator, with or without the use of patient motion detection or physiologic gating.

The control console will support the PreScision feature with one unflattened beam energy labeled as "7UF" to differentiate from the previous 6 MV unflattened beam energy used by the predicate Stereo feature. The 7UF option replaces the existing "Stereo" option previously cleared under the PRIMUSTM (K993425) and ONCORTM (K031764, K060225) and ARTISTE (K072585) devices.

The unflattened X-Ray photon energy spectrum is similar to the 6 MV energy spectrum as used by the PRIMUSTM, ONCORTM, ARTISTE Linear Accelerator systems for the predicate Stereo option and is similar to the energy spectrum of the TomoTherapy Hi-Art system as described in Section 11, Design Description.

The SIEMENS linear accelerator product requirements for the PreScisionTM option consists of the following:

A SIEMENS ARTISTETM, ONCORTM or PRIMUSTM Family of Linear Accelerators with the minimum configuration of:
- COHERENCETM Therapist Workspace or the syngo® Radiation Therapist (RTT) with embedded PRIMEVIEWTM Record and Verify system or the RT ExpressTM system for the ONCORTM or ARTISTETM linear accelerator systems.
- PRIMEVEIW 3i Record and Verify system used with the PRIMUSTM linear accelerator system.
- 58 leaf multi-leaf collimator (MLC) marketed as 3D-MLC, 82 leaf MLC marketed as OPTIFOCUSTM or the 160 Leaf MLC for:
  - Stereotactic Radiotherapy
  - Stereotactic Radiosurgery
  - Fixed fields,
  - Auto-sequenced,
  - Arc (Rotation) and
  - Intensity Modulated Radiation Therapy (IMRT) treatment delivery methods.
- MLC interface to support the SIEMENS ModuLeaf MLC (K030609) for precision Stereotactic or Stereotactic Radiosurgery Radiation Therapy Treatments.
- Gating interface to support Third party, cleared, gating devices for physiologic or patient motion detection.
- Stereotactic mode to support Third party, cleared, stereotactic hardware and patient fixation positioning devices.
- An amorphous Silicon (aSi) flat panel electronic portal imaging device (EPID) marketed as OPTIVEUE 1000ST
- patient treatment couch; 550 TtT (K050422), or the ZXTTM (K910971).

Refer to Section 11 Design Description, for the Product Specification regarding these specific product features.

**General Safety and Effectiveness:**

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 risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software development, verification of
requirements and validation testing. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Intended Use:

The intended use of the SIEMENS branded ARTISTETM, ONCORTM and PRIMUSTM family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The LINAC is a high-dose and high-dose rate medical linear accelerator optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT) and when used in conjunction with the PreScisionTM option, supports precision stereotactic applications. The stereotactic applications include single-session radiosurgery, fractionated stereotactic radiation therapy, fractionated stereotactic intensity modulated radiation therapy for lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

The syngo® Suite for Oncology Workspaces:

The syngo® workspaces includes a number of syngo® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

Summary:

In summary, it is SIEMENS’ belief that the addition of the PreScision option for enhanced stereotactic radiation therapy and stereotactic radiosurgery (SRT / SRS) does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.
Ms. Christine Dunbar  
Senior Regulatory Affairs Specialist  
Siemens Medical Solutions, USA, Inc.  
Oncology Care Systems  
4040 Nelson Avenue  
CONCORD CA  94520

Re:  K087775  
Trade/Device Name: PreScision™ Option  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: September 19, 2008  
Received: September 22, 2008

Dear Ms. Dunbar:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers; based on the regulation number at the top of this letter.

<table>
<thead>
<tr>
<th>Regulation Reference</th>
<th>Description</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 876.xxx</td>
<td>Gastroenterology/Renal/Urology</td>
<td>(240) 276-0115</td>
</tr>
<tr>
<td>21 CFR 884.xxx</td>
<td>Obstetrics/Gynecology</td>
<td>(240) 276-0115</td>
</tr>
<tr>
<td>21 CFR 892.xxx</td>
<td>Radiology</td>
<td>(240) 276-0120</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>(240) 276-0100</td>
</tr>
</tbody>
</table>

Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometrics’ (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.support/index.html.

Sincerely yours,

[Signature]

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Section 4

Indication For Use Statement

510(k) Number (if known): K082775

Device Name: PreScision™ Option

Indications for Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The LINAC is a high-dose and high dose rate medical linear accelerator optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT) and when used in conjunction with the PreScision™ option, supports precision stereotactic applications. The stereotactic applications include single-session radiosurgery, fractionated stereotactic radiation therapy, fractionated stereotactic intensity modulated radiation therapy for lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

The syngo® Suite for Oncology Workspaces:

The syngo® workspaces includes a number of syngo® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)