K092145

SEP 18 2009

Siemens Medical Solutions USA, Inc.
Oncology Care Systems

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

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Email: christine.dunbar.ext@siemens.com

Proprietary Name: 160MLC™ Option

Common Name: An accessory to: Accelerator, Linear, Medical

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

PRODUCT	Clearance	Claim of Equivalence For:
SIEMENS ARTISTE™	K072485	The Siemens branded Linear Accelerator with the 160 leaf MLC and the *syngo®* Suite for Oncology Workspaces including the *syngo®* RT Therapist and RT Therapist Express.
SIEMENS ONCOR™ Expression	K060226	ONCOR™ linear accelerator families and COHERENCE Workspaces (or the re-branded *syngo®* Suite for Oncology Workspaces), RT Therapist workspace with the PRIMEVIEW V&R system, the 82 leaf MLC marketed as OPTIFOCUS™, the Flat Panel device marketed as the OPTIVUE™ and the Mega-Voltage Cone Beam technology marketed as MVision™ and Adaptive Targeting™.
SIEMENS PreScision™ Option	K082775	Establishes the basic hardware/firmware and software components across all of Siemens branded Linear Accelerators for the purposes SE and conformity to standards testing at the device level. Indicates common features between Siemens branded Linear Accelerators for interchangeability of device accessories and options. Supports increased dose rate and Enhanced Stereotactic Technique (EST) for the delivery of high precision radiation therapy when used with an 82 leaf, 160 leaf or Third Party Multi-Leaf Collimators or stereotactic accessories.

The ARTISTE™ and ONCOR™ family of linear accelerators with the 160MLC™ Option as described in this premarket notification has similar intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary:

Within the submission the following internal naming conventions are used:

Market Name	Internal naming convention
ARTISTE™	ARTISTE™ linear accelerator and ACCEL release 4.x+
ONCOR™ Expression	ONCOR™ linear accelerator and ACCEL release 2.x+
ONCOR™ Avant-Garde	ONCOR™ linear accelerator and ACCEL release 1.x+ and 2.x+
PRIMEVIEW™	Siemens proprietary verify and record system. The *syngo®* based PRIMEVIEW is hosted on the COHERENCE™ Therapist Workspace. The syngo base version is marketed as PRIMEVIEW3i and is used on the PRIMUS™ linear accelerator systems.
COHERENCE™ Therapist Workspace	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.
MVCB - MVision™	Mega-Voltage Cone Beam – a method of obtaining 3 dimensional data for portal imaging.
160 MLC™	160-leaf multi-leaf collimator
OPTIFOCUS™	82-leaf multi-leaf collimator
58 MLC	58 leaf multi-leaf collimator
OPTIVUE™	aSi flat panel electronic portal imaging device (EPID) AL7 model
OPTIVUE 1000ST	aSi flat panel electronic portal imaging device (EPID) AG9 model
syngo® Therapist Workspace, RTT Express™	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 ARTISTE™ linear accelerator system.
syngo® Suite for Oncology Workspaces	*Syngo* based workstation, re-branded COHERENCE workspaces.
syngo®	Siemens proprietary software architecture and hosting SIEMENS software applications organized by task cards on a dedicated workstation.
Sys_VB35	System Software, version VB35 for ONCOR R2.2.

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

Technological Characteristics:

The 160MLC™ Option:

The 160MLC™ Option is an integral feature of the currently cleared SIEMENS ARTISTE™ system and is intended to be marketed as an optional upgrade to the ONCOR™ Klystron class family of medical linear accelerator devices. The basic design, safety features and function of the 160-leaf Multi-Leaf Collimator and the ONCOR Linear Accelerator remain unchanged from their currently cleared intended use and functions. The 160MLC™ supports the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation using the conventional linear accelerator. The 160MLC, in conjunction with the Linear Accelerator and control systems, are used for the delivery of X-Ray photon or electron energy for precise treatment of lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

The 160MLC™ option supports the dynamic IMRT and dynamic Arc delivery of up to 1,000 (± 2%) MU / Minute X-Ray photon beam using a calibrated MV photon energy spectrum with an edge position accuracy at isocenter of 0.5mm (± 0.5mm) with minimal leakage and penumbra.

Refer to Section 11- Design Description, for the Product Specification regarding these specific modifications.

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 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 linear accelerator 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 a multi-leaf collimator, supports precision radiation therapy treatment. The radiation therapy treatment may include single-session treatment, fractionated radiation therapy treatments, fractionated intensity modulated radiation therapy (IMRT) for lesions, tumors and conditions anywhere in the body where radiation therapy is indicated.

Additionally, the SIEMENS branded linear accelerators includes as an optional feature, a 160 leaf multi-leaf collimator that is marketed as 160MLC™. The 160MLC is provided to assist the radiation oncologist in the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. The indications for use for the 160MLC Option remains unchanged from the previously cleared 160MLC used on the ARTISTE linear accelerator (K072485).

The *syngo*® Suite for Oncology Workspaces:

The *syngo*® Suite for Oncology 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 160MLC™ option to the ONCOR linear accelerators for high precision radiation therapy does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
CONCORD CA 94520

Re: K092145
Trade/Device Name: 160MLC™ Option
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 10, 2009
Received: July 15, 2009

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 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.

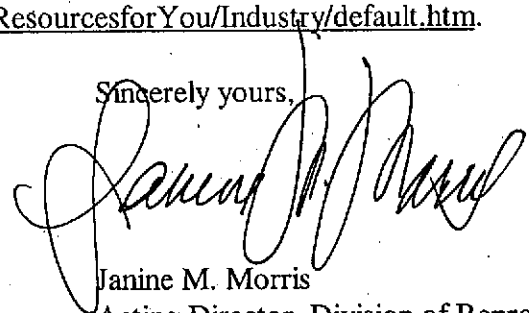
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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): K092145

Device Name: 160MLC™ Option

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092145

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)