K121295

Siemens Medical Solutions USA, Inc.
Radiation Oncology

Section 5

JUN 27 2012

510(k) Summary

Date Prepared: April 27, 2012
Date Updated: June 25, 2012

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

Contact: Christine Dunbar
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Proprietary Name: ARTISTE™ Solution with SYS_VC10

Common Name: Medical Charged-Particle Radiation Therapy System

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

Product	510(k) Clearance / Date	Claim of Equivalence for:
ARTISTE™ Solution with SYS-VB50 update with Control Console 12 & with *syngo*® RTT Connect v4.2, *syngo*® Oncologist v4.2	K103606 / April 15, 2011	ARTISTE™ Solution with SYS-VC10 update with Control Console 13 & with *syngo*® RTT v4.3, *syngo*® Oncologist v4.3
SIMTEC IM_MAXX 2 Intensity Modulation Radiation Therapy (IMRT)	K052315 / Sept. 22, 2005	ARTISTE™ Solution with the SYS_VC10 & *syngo*® RT Therapist v4.3 new feature mARC
Varian Trilogy™ System with RapidArc.	K072916 / Nov. 9, 2007	ARTISTE™ Solution with the SYS_VC10 & *syngo*® RT Therapist v4.3 with new feature

Product	510(k) Clearance / Date	Claim of Equivalence for:
Aka VMAT (volumetric modulated arc therapy).		mARC (also called rotational IMRT)
syngo® Expert I option on MAGNETOM Systems	K052423 / Jan. 13, 2006	ARTISTE™ Solution with the SYS_VC10 & *syngo*® RT Therapist v4.3 & Oncologist v4.3 with new feature *syngo*® Expert i

The ARTISTE™ Solution SYS_VC10 Update as described in this premarket notification has the same intended use and fundamental scientific technical characteristics as the predicate devices, or specific features of the predicate devices listed above.

Description Summary - ARTISTE™ Solution with SYS_VC10 Update

Technological Characteristics:

The ARTISTE™ Solution SYS_VC10 is a software update to the ARTISTE family of medical linear accelerators and is intend to update customers with optional new features for systems with the *syngo*® RT Therapist, v4.1 and RT Therapist Connect v4.2 Workspaces for the currently cleared ARTISTE systems. Additionally, the SYS_VC10 software update also includes an (optional) software update for the *syngo*® RT Oncologist v4.2 workspace. The SYS_VC10 update will bring the *syngo*® RT Therapist and the *syngo*® RT Oncologist workspaces to version 4.3.

This update is intended to be backwards compatible to the currently cleared ONCOR and PRIMUS family of medical linear accelerators and their Control Consoles (v9.0+ & v11.0, v12), the RT Therapist (v2.1a or v2.2+) and Oncologist v2.0 & v2.4 workspaces. These older versions can be migrated up to the current release (RTT / ONC. v4.3) and Control Console 13.

The technological characteristics and fundamental technology of the ARTISTE™ Solution remain unchanged from the currently cleared device (K103606).

The *syngo*® Software Architecture:

The *syngo*® Suite for Oncology Workspace clinically focused software utilizes the proprietary *syngo*® software architecture design provides a method of delivering customized software applications based on the modality as clinically supporting packages. From these applications SIEMENS utilizes, as part of the Oncology clinical focus package, multiple applications for patient set-up and position verification, treatment localization, treatment verification, portal imaging as well as data processing, image

reformatting, display and printing. The currently cleared COHERENCE™ and *syngo*® products also include an array of image-oriented software tools, support for DICOM connectivity and the Siemens Remote Service option.

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 means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. 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 systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT), modulated arc therapy (mARC) and precision stereotactic radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

<u>The *syngo*® Suite for Oncology Workspaces:</u>

The *syngo*® workspaces includes a number of *syngo*® based, clinically focused advanced software applications that include patient data management, remote user communication within a local network, and the viewing, processing, manipulation, filming, and archiving of medical images.

The *syngo*® RT Therapist Workspace v4.3, contains software applications that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The *syngo*® RT Therapist Workspace v4.3, can be interfaced with third party devices conforming to the DICOM Standard.

The *syngo*® RT Oncologist Workspace v4.3 permits localization, contouring, segmentation, image calibration, and review of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

Substantial Equivalence:

The Substantial Equivalence comparison chart demonstrates the comparison of the technological characteristics of the new features and their currently cleared predicate devices.

The new features for the *syngo*® RTT and Oncologist Workspaces v4.3 does not change the intended use of the original *syngo*® RT Therapist or Oncologist Workspaces or the Siemens branded Linear Accelerator Systems.

Bench Testing:

Bench verification testing in the form of Unit (UT), Integration (IT), Sub-System Integration (SSIT), and System Integration (SIT) testing was performed to evaluate the performance and functionality of the new feature and software updates. All testable requirements have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process (PDP).

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plans.

Non-Clinical Test Results:

Validation of the new features for *syngo*® RT Therapist Workspace, v4.3 and Oncologist v4.3 has been performed at the System test (ST) level on production prototype devices by appropriately trained and knowledgeable test personnel. System level validation and regression testing has been performed successfully, demonstrating that the software meets the acceptance criteria as noted in the system test plans and the Software Product Quality Management Plan (SwPQMP).

Testing to Consensus Standards:

The Siemens branded Linear Accelerators with the new features have been tested to meet the requirements for conformity (where applicable) to multiple industry standards.

Substantial Equivalence to Predicates:

The successful verification and validation testing to the meet the new software features and device requirements of the *syngo*® RT Therapist and *syngo*® RT Oncologist workspaces software v4.3, in addition to the updated ARTISTE™ Solution Linear Accelerator functional requirements, is intended to support the claim of substantial equivalence to the currently cleared predicates as indicated above.

Summary:

In summary, it is SIEMENS' opinion that the ARTISTE with the Sys_VC10 update 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

JUN 27 2012

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

Re: K121295
Trade/Device Name: ARTISTE™ Solution with SYS_VC10
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 27, 2012
Received: April 30, 2012

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Siemens Medical Solutions USA, Inc.
Radiation Oncology

Section 4

Indication for Use Statement

510(k) Number (if known): K121295

Device Name: ARTISTE™ Solution with SYS_VC10

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 In Vitro Diagnostic Devices (OIVD)

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

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121295