K123812

MAR 1 2013

Section 5

510(k) Summary

Date Prepared: December 05, 2012
Date Updated February 12, 2013

Submitter: Siemens Medical Solutions USA, Inc.
Radiation Oncology
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Proprietary Name: COHERENCE™ RT Therapist Connect Workspace, v2.3
And the optional 3rd party OIS Connectivity System

Common Name: Accessory To; 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:
COHERENCE™ RT Therapist v2.1a with Control Console 9.2.	K090683 / May 08, 2009	COHERENCE™ RT Therapist Connect Workspace, for RT Therapist with Software update Sys_VA32a (RTTC v2.3) and Control Console 9.2.
ONCOR™ with 160MLC Option with RTT v2.2 & with Control Console 11.0.	K092145 / March 13, 2009	COHERENCE™ RT Therapist Connect Workspace for RT Therapist with Software update Sys_VA32a (RTTC v2.3) and Control Console 11.0.
ONCOR™ Expression with RTT v2.0+ & with Control Console 9.0+	K060226 / Mar. 15, 2006	COHERENCE™ RT Therapist Connect Workspace for RT Therapist with Software update Sys_VA32a (RTTC v2.3) and Control Console 9.2.

The update to the COHERENCE™ RT Therapist Connect Workspace, v2.3 as described in this premarket notification has the same intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary

COHERENCE™ RT Therapist Connect Workspace, v2.3:

Technological Characteristics:

The COHERENCE™ RT Therapist Connect Workspace v2.3 release is intended to update customers with the currently released COHERENCE™ RT Therapist Connect Workspace with versions v2.1a (ONCOR / PRIMUS systems). The technological characteristics of the COHERENCE™ RT Therapist Connect Workspace v2.3 remain unchanged from the currently cleared products.

The *syngo*® Software Architecture:

The COHERENCE™ RT Therapist Connect 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, Siemens Remote Service, and virus protection 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 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.

COHERENCE™ RT Therapist is a component of the linear accelerator system and is based on the *syngo*® architecture. It enables patient management, patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

COHERENCE™ RT Therapist Workspace Connect v2.3 can be interfaced with 3rd party devices conforming to the DICOM standard.

Substantial Equivalence:

The Substantial Equivalence comparison chart demonstrates the comparison of the technological characteristics of the COHERENCE™ RT Therapist Connect Workspace v2.3 update to the currently cleared predicate devices.

The COHERENCE™ RT Therapist Connect Workspace v2.3, does not change the intended use of the original COHERENCE™ RT Therapist Connect Workspace v2.1a or the Siemens branded Linear Accelerator Systems.

Bench Testing:

Bench testing in the form of Unit, Integration and System Integration testing was performed to evaluate the performance and functionality of the software update v2.3 for the RT Therapist Connect and regression testing the Control Console, versions 9.2 and 11.0. All testable requirements in the Product Requirements Specifications (PRS) for the Sys_VA32a project, and additionally the specific requirements for the implementation of the third party OIS marketed by 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.

Non-Clinical Test Results:

Validation of the COHERENCE™ RT Therapist Connect Workspace v2.3, implementation of the optional third party OIS with the low voltage electronic switch and regression testing with Control Consoles 9.2.18 and 11.0.212 has been performed at the System test 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.

Testing to Consensus Standards:

The COHERENCE™ RT Therapist Connect Workspace, v2.3, Control Console and the new electronic switch to support the third party OIS implementation have been tested to meet the requirements for conformity (where applicable) to the following standards:

- IEC 60601-1-4:1996+ A1: 1999 – Medical Electrical Equipment: Part 1-4: General requirements for Collateral Standard: Programmable Electrical Medical Systems
- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- IEC 61217 (2007), Radiotherapy equipment - Coordinates, movements, and scales
- IEC 62274:2005 Medical Electrical Equipment, Safety of Radiotherapy Record and Verify Systems

Substantial Equivalence to Predicates:

The verification testing to the Product requirements for the RT Therapist Connect workspace, validation of the intended use, and the regression testing to the existing RT Therapist Connect software and Control Console functional requirements, is intended to support the claim of substantial equivalence to the following predicates:

- The COHERENCE™ RT Therapist Connect v2.1a. & CC 9.2 (K090683),
- The ONCOR with 160MLC option with the RTT v2.2 & CC 11.0 (K092145) and

- The ONCOR and PRIMUS with the RTT v2.0 and 2.1 & CC 9.0+(K060226)

Summary:

In summary, it is SIEMENS' opinion that the COHERENCE™ RT Therapist Connect Workspace v2.3 update including the optional 3rd party OIS Connectivity systems requiring the low voltage electronic switch where configured, 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 Center – WO66-G609
Silver Spring, MD 20993-0002

Christine Dunbar
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Radiation Oncology
757A Arnold Drive
MARTINEZ CA 94553

March 1, 2013

Re: K123812
Trade/Device Name: COHERENCE™ RT Therapist Connect Workspace
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 7, 2012
Received: January 15, 2013

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

Enclosure

Indications for Use

510(k) Number (if known): K123812

Device Name: COHERENCE™ RT Therapist Connect Workspace, v2.3

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123812