K060633

Siemens Medical Solutions USA, Inc.
Oncology Care Systems

MAY 1 2006

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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Proprietary Name: COHERENCE™ Workspaces (Physicist, Oncologist)

Common Name: Accelerator, Linear, Medical (Accessories to)

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

PRODUCT	Clearance	Claim of Equivalence For:
ONCOR Avant-Garde with COHERENCE Workspaces	K031764	COHERENCE Workspaces, includes the addition of the COHERENCE Physicist and an upgrade to the Oncologist workspaces.
LEONARDO	K040970	Syngo based applications on COHERENCE Workspaces
RIT 113	K935928	Quality Assurance software applications.

Description Summary:

Within the submission the following internal naming conventions are used:

Market Name	Internal naming convention
ONCOR Avant-Garde	ONCOR linear accelerator and ACCEL release 1
COHERENCE Oncology Workspaces	Suite of oncology focused workspaces
COHERENCE Therapist Workspace	RTT Workspace
COHERENCE Oncologist Workspace	MD Workspace

Market Name	Internal naming convention
COHERENCE Data Conditioning	Syngo based software application consisting of several micro-applications. Referred to as "CDC" and consists of: o Image Conditioner o Image Calibration
LEONARDO	*Syngo* based workstation
Machine Quality Assurance	MQA - *Syngo* based software application consisting of several micro-applications used for: o Test Preparation o Analysis Tools o Documentation of results.
PRIMEVIEW3i Verify and Record system	PRIMEVIEW3i Verify and Record system has a 510(k) Non-Filing Justification on file because the application differs only in name from the COHERENCE Therapist workspace (K031764). The PRIMEVIEW3i V & R is used with the PRIMUS Linear Accelerator.
syngo	Siemens proprietary software architecture and hosting Siemens software applications organized by task cards on a dedicated workstation.
TPS	Treatment Planning System

COHERENCE Workspaces (Physicist, Oncologist):

The COHERENCE Physicist Workspace is an optional accessory to a medical linear accelerator and is based on the previously cleared ONCOR Avant-Garde with COHERENCE Workspaces (K031764) and *syngo*™ software design architecture previously cleared on the LEONARDO workstation (K040970). The Quality Assurance software applications support the COHERENCE Data Conditioner and customer configurable Quality Assurance applications that Siemens believes are substantially equivalent to those previously cleared on the RIT 113 Film Analysis System (K935928).

The rationale for the development of this product is as follows:

- The American Association of Physicist in Medicine, (AAPM) currently defines the standard of care for the quality assurance practices[1], which are defined in a written QA program and performed by a licensed Medical Physicist, a Medical Oncologist, Dosimetrist and/or Radiation Therapist as required by JCAHO[2] and other guidelines. The COHERENCE Physicist workspace will provide a dedicated workspace to enable timely quality practices utilizing advanced software packages.

- The currently cleared ONCOR Avant-Garde with COHERENCE Workspaces (K031764) facilitates the quality assurance practices and procedures utilizing manual input of data by the Medical Physicist, Medical Oncologist, Dosimetrist and/or Radiation Therapist. The QA data may be derived from film based dosimetry, electronic portal imaging devices (EPID), ion chambers and other calibration devices, however, the data can only be processed using software based applications if the electronic data conforms to the DICOM RT standard. This

[1] Kutcher et al: Report of AAPM Radiation Therapy Committee Task Group 40, Medical Physics, Vol. 21, No. 4, April 1994.
[2] Joint Commission on the Accreditation of Healthcare Organizations

means that the collection of QA data from a variety of sources, specifically electronic image scanners who's output is in a Non-DICOM standard format such as a BITMAP or .TIFF file, cannot be used. The Non-DICOM conforming data requires manual input into electronic spreadsheets or manual data entry into software processing applications (MS Excel™ file). The required output is generally a written report, printed and filed as per the department record retention requirements.

The Physicist workspace will support the current manual methodologies for managing quality assurance data using the ONCOR COHERENCE Therapist (or PRIMEVIEW3i workspace) as sources of QA data. The Physicist WS will also offer a suite of customizable QA test protocols (user created and configured macros), test analysis and documentation tools.

The Physicist Workspace will support the COHERENCE Data Conditioner software application which allows the input of DICOM and non-DICOM conforming data objects that have been converted from electronically scanned film (bitmap or TIFF format), EPID data and electronic data from analyzers and film digitizers. The new COHERENCE Data Conditioning application will provide a method of importing non-DICOM data from a variety of electronic media, as mentioned above, and provide the user a method of converting the non-DICOM data into DICOM RT standard images. The DICOM RT standard images can then be processed using a combination of the previously cleared *syngo* software applications and the new conditioning, calibration and analysis software applications as described in this submission. (See comparison table).

Syngo™:
The original COHERENCE Workspace software (K031764) was based on the software architecture of the previously cleared *syngo* software (K010938) and allows for a standardized graphical user interface across Siemens medical products. The *syngo*-based software design consists of task cards allowing for a selection of modules of common software applications for image acquisition, reconstruction, post-processing, display, and archiving across the Siemens medical product lines. The latest in *syngo* software applications for the reconstruction, post- processing, manipulation, display and archiving of images are included in the previously cleared workstation under the market name of LEONARDO (K040970).

As part of the Siemens Medical Solutions family of workstations, the *syngo* based workstations (Oncology Care System calls a "workstation" a "workspace") offers a configurable selection of software applications depending on the type of *syngo* package that is required for a specific modality. There are multiple applications in common across all Siemens imaging modalities as previously mentioned. In this submission, the COHERENCE Data Conditioner and Adaptive Targeting software modules are shared across several COHERENCE Workspaces.

COHERENCE Oncologist Workspace, Version 2.0.
The previously cleared COHERENCE Oncologist Workspace provided a *syngo* based interface for 2D, 3D, and volumetric targeting of the radiation treatment using the Portal Imaging application for the purposes of patient position localization and setup. This revision to the Oncologist workspace adds:

- **COHERENCE Data Conditioner**
  The same syngo based software application module to enable the medical physicist and/or oncologist a method to convert non-DICOM data into DICOM RT conforming data where non image dependent information is missing such as gantry angle, collimator angle, etc.

- **Adaptive Targeting™**
  Improvements to the volume targeting application for advanced Image Guided Radiation Therapy (IGRT) is featured in the new *syngo* based Adaptive Targeting application module, which supports alignment of 3D planning data for the purposes of patient setup and patient position localization. The Adaptive Targeting application supports the automatic calculation of the table offsets when comparing 3D planning data and current 2D or 3D portal imaging.

Note:
Refer to Section 11 Design Description, for the design description and functional specifications of these new features.

The COHERENCE Physicist and Oncologist Workspaces, will also be available as individual purchased options to existing Siemens PRIMUS and ONCOR medical linear accelerator product lines upon receipt of FDA market clearance notification.

Intended Use:

The intended use of the COHERENCE Workspaces are as accessories to the linear accelerator systems to aid and support in the quality assurance, planning and delivery of x-ray radiation for the therapeutic treatment of cancer.

The COHERENCE Workspaces encompasses a number of *syngo* software applications who's indication for use include the viewing, manipulation, filming, communications, and archiving of medical images and data on exchange media.

The COHERENCE™ Physicist Workspace can be configured with a variety of *syngo*™ based software options and is intended for use to aid and support quality assurance practices for radiation therapy linear accelerators and their accessories such as Multi-Leaf Collimators, EPIDs, and other electronic devices.

The COHERENCE Physicist workspace has similar technical characteristics as the COHERENCE™ Therapist and Oncologist workspace accessory devices and is to be considered an additional accessory to the previously cleared Primus (K993425) and ONCOR (K031764) radiotherapy linear accelerator product lines.

The COHERENCE Oncologist Workspace permits localization, contouring, image calibration and conditioning, and review of treatment parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

Also as part of the COHERENCE Oncologist V2.0 revision, the addition of the Adaptive Targeting application enhances the utilization of patient position localization data derived from 3D imaging applications or imported from another 3D imaging system (i.e. CT or Megavoltage Cone Beam). The Adaptive Targeting application can automatically align the 3D reconstructed image data with the 3D planning data imported from a Treatment Planning System using the calibrated machine isocenter and calculate position offsets. The offset amount can be transferred to the COHERENCE Therapist Workspace then to the treatment table to align the patient's setup position. The image alignment and offset calculation can be performed using both manual and automated tools. Adaptive Targeting is intended to provide a method by which the physician can improve treatment positioning accuracy in conventional fractionated radiation therapy.

The intended use for the COHERENCE Oncologist 2.0 workspace remains unchanged from the previously cleared COHERENCE Oncologist workspace (K031764).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 1 2006

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

Re: K060633
Trade/Device Name: Coherence™ Workspaces (Physicist™ and Oncologist™)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 7, 2006
Received: March 9, 2006

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 (Premarket Approval), 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:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Siemens Medical Solutions USA, Inc.
Oncology Care Systems

Section 4

Indication For Use Statement

510(k) Number (if known): K060633

Device Name: COHERENCE™ Workspaces (Physicist, Oncologist)

Indications for Use:

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The COHERENCE Workspaces encompasses a number of *syngo* software applications who's indication for use include the viewing, manipulation, filming, communications, and archiving of medical images and data on exchange media.

The COHERENCE Oncologist Workspace permits localization, contouring, image calibration and conditioning, and review of treatment parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy. The indications for use for the COHERENCE Oncologist 2.0 workspace remain unchanged from the previously cleared COHERENCE Oncologist workspace (K031764).

The COHERENCE Physicist Workspace is a *syngo* software application package for the use with radiation therapy devices for viewing, manipulation, image calibration and conditioning, communication and storage of medical images and data on exchange media; and as a quality assurance tool for radiation therapy linear accelerators and their accessories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagamma

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060633

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)