K031764

SEP - 5 2003

Tab A
510(k) Summary

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

Contact: Ken Nehmer
Manager of Regulatory Affairs

Phone: (925)602-8011
Fax: (925)602-8008
Email: ken.nehmer@siemens.com

Proprietary Name: ONCOR Avant-Garde with COHERENCE Workspaces

Common Name: Accelerator, Linear, Medical

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

PRIMUS	K993425	(equivalence for ONCOR Avant-Garde linear accelerator)
Mevatron KD2	K862339	(equivalence for ONCOR Avant-Garde linear accelerator)
BeamView	K903139	(equivalence for OPTIVUE Electronic Portal Imaging Device)
PortalVision	K003636	(equivalence for OPTIVUE Electronic Portal Imaging Device)
58 leaf MLC	K953894	(equivalence for OPTIFOCUS 82 leaf multi-leaf collimator)
(VSIM) Dosimetrist	K022036	(equivalence for COHERENCE Workspaces)
syngo Workstation	K010938	(equivalence for COHERENCE Workspaces)
LANTIS Treatstation	K972275	(equivalence for COHERENCE Workspaces)

Description:

Within the submission the following internal naming conventions are used:

Market Name	Internal naming convention
ONCOR Avant-Garde	ACCEL linear accelerator
ONCOR Avant-Garde	ACCEL release 1
COHERENCE Therapist Workspace	RTT Workspace
COHERENCE Oncologist Workspace	MD Workspace
OPTIFOCUS	82-leaf multi-leaf collimator
OPTIVUE	aSi flat panel electronic portal imaging device (EPID)

The ONCOR Avant-Garde is a medical linear accelerator based on the previously cleared PRIMUS design architecture (K993425) and includes an amorphous Silicon (aSi) flat panel electronic portal imaging device (EPID), an 82 leaf multi-leaf collimator (MLC), and COHERENCE Therapist Workspace software. Refer to

Tab H through Tab J for detailed information regarding the ONCOR Avant-Garde linear accelerator requirements and specifications.

The aSi flat panel (marketed as OPTIVUE) is integrated into the ONCOR Avant-Garde system and aids in positioning verification by visualizing patient positioning markers and/or anatomical references. The flat panel detects radiation from the linear accelerator, this information is then interpreted via software to obtain visualization of patient positioning markers and/or anatomical structures. The OPTIVUE flat panel detector is a digital x-ray camera comprised of sensors. These sensors are amorphous Silicon (aSi) photo diodes that are placed on a glass substrate with scintillator coating. The incident x-rays are converted by the scintillator screen. The converted x-ray signals are then amplified and converted to a digital format. This digital formatted data is then transmitted to the data acquisition unit or frame grabber and interpreted into positioning images. The OPTIVUE includes automated deployment of the flat panel that eliminates the need to enter the treatment room to acquire portal images, thus improving the efficiency of patient treatments. The intended use of the OPTIVUE is the same as the BeamView EPID that was previously cleared via K903139. Refer to Tab L for detailed information regarding the OPTIVUE flat panel EPID specifications.

The 82 leaf multi-leaf collimator (marketed as OPTIFOCUS) is integrated into the ONCOR Avant-Garde system and allows for user definable optimization of resolution for target conformation. The OPTIFOCUS is based on the same architectural design as the previously cleared 58 leaf MLC (K953894). The increase in the number of leaves in the collimator allows for increased conformal shape resolution. Refer to Tab P for detailed information regarding the OPTIFOCUS 82 leaf MLC specifications.

The COHERENCE Workspace software is based on the architecture of the previously cleared syngo software (K010938) and allows for a standard graphical user interface across Siemens medical products. Efficiency can be improved by this standard graphical interface in that common tasks are presented similarly across the Siemens medical product line.

The COHERENCE Therapist Workspace software integrates the linear accelerator processes of setup, setup verification, patient positioning, patient positioning verification, treatment delivery, and recording. The COHERENCE Therapist Workspace provides a simple interface for 2D, 3D, and volumetric targeting of the radiation treatment. Patient management is facilitated by easy access to all pertinent patient data with the integration of previously cleared functionality. The Therapist Workspace integrates various functions from previously cleared products (ie. VSIM marketed as COHERENCE Dosimetrist (K022036), syngo Workstation (K010938), and LANTIS Treatstation marketed as PRIMEVIEW (K972275). The COHERENCE Therapist Workspace is designed to provide the necessary tools to facilitate the Therapist in their daily clinical workflow.

The COHERENCE Oncologist Workspace software is an option for the ONCOR Avant-Garde linear accelerator and provides access to patient data, images, and tools needed to help facilitate the Oncologist in performing accurate and timely clinical decisions. Multi-modality images can be loaded and manipulated with the advanced tools allowing for efficient localization and contouring of tumors and critical anatomical structures. The COHERENCE Oncologist Workspace provides access to all radiation therapy plans, visualization of suggested alternate plans, and comparisons with prior treatment plan data. In addition, it provides for treatment verification of patients with access to pertinent treatment data allowing for full treatment review. The COHERENCE Oncologist Workspace is based on the previously cleared syngo architecture (K010938). The COHERENCE Oncologist Workspace is also based on functionality cleared under VSIM via K022036 and permits localization, contouring, image conditioning, and review of treatment parameters. In addition, there are tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy. The COHERENCE Oncologist Workspace is designed to provide the necessary tools to facilitate the Radiation Oncologist in their daily clinical workflow.

The OPTIVUE, OPTIFOCUS, and COHERENCE Therapist Workspace, may also be available as individual purchased options to existing Siemens medical linear accelerators.

Intended Use:

The intended use of the ONCOR Avant-Garde linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer. The ONCOR Avant-Garde includes an Electronic Portal Imaging Device (EPID) that will be marketed as OPTIVUE and is used for the verification of the treatment field and shielding blocks in relation to patient positioning markers and/or anatomical landmarks in radiotherapy treatment. OPTIVUE will also allow for verification of the exit dose in radiotherapy treatment. The intended use of the OPTIVUE is similar to the BeamView EPID that was previously cleared via K903139. The intended use of the OPTIVUE is to provide patient positioning reference data.

Additionally, the ONCOR Avant-Garde includes an 82 leaf multi-leaf collimator that will be marketed as OPTIFOCUS. The OPTIFOCUS MLC 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. In a static mode, the MLC performs the same function as the customized shadow blocks. In a dynamic mode, a series of MLC leaf positions can be indexed to either dose fraction or gantry angle to create a changing beam shape while the radiation beam is on to create a three dimensional dose distribution. The intended use of the OPTIFOCUS is unchanged from the previously cleared 58 leaf MLC (K953894).

The COHERENCE Therapist Workspace is included with the ONCOR Avant-Garde system and is based on the previously cleared syngo architecture (K010938). The COHERENCE Therapist Workspace is a software application that permits patient data management, patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The Therapist Workspace integrates various functions from previously cleared products (ie. VSIM marketed as COHERENCE Dosimetrist (K022036), syngo Workstation (K010938), and LANTIS Treatstation marketed as PRIMEVIEW (K972275).

The COHERENCE Oncologist Workspace is an option to the ONCOR Avant-Garde system and is also based on the previously cleared syngo architecture (K010938). The COHERENCE Oncologist Workspace is based on functionality cleared under VSIM via K022036 and permits localization, contouring, image conditioning, and review of treatment parameters. In addition, there are tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

The intended uses of the ONCOR Avant-Garde including the OPTIVUE flat panel EPID and OPTIFOCUS multi-leaf collimator remain unchanged from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2003

Mr. Ken Nehmer
Manager of Regulatory Affairs
Siemens Medical Solutions
Oncology Care Systems Group
4040 Nelson Avenue
CONCORD CA 94520

Re: K031764
Trade/Device Name: ONCOR Avant-Garde with COHERENCE Workspaces
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: June 5, 2003
Received: June 9, 2003

Dear Mr. Nehmer:

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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number (if known): K031764

Device Name: ONCOR Avant-Garde with COHERENCE Workspaces

Indications for Use:

The intended use of the ONCOR Avant-Garde linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer. The ONCOR Avant-Garde includes an Electronic Portal Imaging Device (EPID) that will be marketed as OPTIVUE and is used for the verification of the treatment field and shielding blocks in relation to patient positioning markers and/or anatomical landmarks in radiotherapy treatment. OPTIVUE will also allow for verification of the exit dose in radiotherapy treatment. Additionally, the ONCOR Avant-Garde includes an 82 leaf multi-leaf collimator that will be marketed as OPTIFOCUS. The OPTIFOCUS MLC 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. In a static mode, the MLC performs the same function as the customized shadow blocks. In a dynamic mode, a series of MLC leaf positions can be indexed to either dose fraction or gantry angle to create a changing beam shape while the radiation beam is on to create a three dimensional dose distribution.

The COHERENCE Workspaces (Therapist and Oncologist) encompasses a number of syngo software applications for viewing, processing, filming, and archiving of medical images. The COHERENCE Therapist and Oncologist Workspaces are two of the software applications that are offered on the syngo workstation (K010938). COHERENCE Therapist Workspace is included in the ONCOR Avant-Garde product. The Therapist Workspace permits patient data management, patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The COHERENCE Oncologist Workspace permits localization, contouring, image 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031764