SIEMENS

K072485

Section 5 510(k) Summary and Statement

Submitter:	Siemens Medical Solutions USA, Inc., Oncology Care Systems
Address:	4040 Nelson Ave. Concord, CA 94520 USA
Phone number:	925-246-8378
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Contact person:	Bill Collins, Manager, Regulatory Affairs
Date prepared:	8/31/2007
Trade name:	ARTÍSTE MV SA™
Device classification:	892.5050/ IYE/Radiology
Substantial equivalence claimed to:	ONCOR EXPRESSION with COHERENCE Workspaces (K060226)

DEC 2 7 2007

Device Description:

The ACCEL system is the internal name for the Siemens program which includes the ONCOR Linear Accelerator product lines. The newest member of the ACCEL systems is the ARTÍSTE MV SA™ Linear Accelerator product. The ARTÍSTE MV SA™ is composed of upgraded hardware, firmware and software as standard features.

Intended use:

The intended use of the ARTÍSTE MV SA™ linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer.

The ARTÍSTE MV SA™ includes an Electronic Portal Imaging Device (EPID), a 160 leaf multi-leaf collimator, and the syngo™ RT Therapist Express Workspace with MVision™.

The syngo™ RT Therapist Express Workspace is a software application that uses syngo™ based applications.

Summary of technological characteristics:

The ARTÍSTE MV SA™ linear accelerator does not have significant changes in materials, energy source or technological characteristics as compared to the predicate device. The intended use, indication for use and the fundamental scientific technology are the same as the predicate device and therefore we believe it is substantially equivalent to the predicate device.

Substantial equivalence:

The ARTÍSTE MV SA™ linear accelerator is substantially equivalent to the ONCOR EXPRESSION with COHERENCE Workspaces (K060226) in that it provides x-ray radiation for therapeutic treatment of cancer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2007

Siemens Medical Solutions USA, Inc.
% Mr. Erik Rodriguez
Senior Software Quality Engineer
Certified Compliance Solutions, Inc. (CCS, Inc)
16787 Bernardo Center Drive
SAN DIEGO CA 92128

Re: K072485
Trade/Device Name: ARTÍSTE MV SA™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 28, 2007
Received: November 28, 2007

Dear Mr. Rodriguez:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Section 4 Indications for Use Statement

510(k) Number: K072485

Device Name: ARTÍSTE MV SA™

Indications for Use:

The intended use of the ARTÍSTE MV SA™ linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer.

The ARTÍSTE MV SA™ includes an Electronic Portal Imaging Device (EPID), a 160 leaf multi-leaf collimator, and the syngo™ RT Therapist Express Workspace with MVision™.

The *syngo*™ RT Therapist Express Workspace is a software application that uses *syngo*™ based applications with these embedded features:

- patient data management, selection and setup by use of a local, on-board database,
- treatment delivery/verification and treatment recording by use of on-board applications,
- Megavoltage Cone Beam acquisition method for acquiring projection data for 3D reconstruction.
- Patient positioning verification by use of the OPTIVUE imaging system, including MVision™(Cone Beam acquisition and reconstruction and the Adaptive Targeting application).

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

(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 K072485