 SEP 2 2 2005

K052315

Tab 1
510(k) Summary

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

Contact: Christine Dunbar CD 8-23-05
Senior Regulatory Affairs Specialist

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Establishment Registration Number 2910081

Proprietary Name: SIMTEC IM-MAXX 2 Option

Common Name: (Accessory To) - Accelerator, Linear, Medical

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

- K993425 – PRIMUS Linear Accelerator, cleared on Nov. 26, 1999.
- K031764 - ONCOR Avant-Garde with COHERENCE Workspaces, cleared on Sept 5, 2003

Historical Information and Device Description:

The radiation therapy treatment technique known as "Intensity Modulation Radiation Therapy" or "IMRT" has its origins in a treatment application where the fractionated irradiation of patients in the conventional 2D method evolved into Automatic Field Sequencing of controlled conformal (3D) step and shoot or arc-radiation therapy.

The Automatic Field Sequencing method is trade-named SIMTEC® (Sequential Intensity Modulated Technology) which was first introduced in the Digital Mevatron™ (K882729) product. A faster version of this technology, trade named SIMTEC IM-MAXX® (internal name is Fast IMRT) was introduced in the PRIMUS™ (K993425) product, which is the predicate for this submission. The IM-MAXX treatment delivery technique is a Static IMRT, also known as "step and shoot" method where nothing moves (MLC leaves or gantry) when the beam is on. This static treatment method has remained unchanged from the IMRT delivery technique first described in the Digital Mevatron product and later in the PRIMUS and ONCOR products.

The SIMTEC IM-MAXX 2 Option (also called IM-MAXX 2) is to be used in conjunction with Siemens radiation therapy linear accelerator systems and its accessories and provides a method of delivering Fast IMRT treatment technique with faster delivery times by modification of the serial communication and jaw movements of the Multi-Leaf Collimator between treatment delivery.

Summary of Technological Characteristics Compared to Predicate Devices:

The SIMTEC IM-MAXX 2 software incorporates no new technological characteristics not currently in the predicate SIMTEC IM-MAXX (FIMRT) option.

The SIMTEC IM-MAXX 2 software consists of:

(1) The original SIMTEC IM-MAXX technology, also referred to as Automatic Field Sequencing (AFS), the software architecture and design has not been modified. The serial communication consists of proprietary communication interfaces based on a Universal Serial Protocol developed by Siemens in accordance to the ANSI 232E standard. To increase the delivery speed of the FIMRT treatment delivery technique, the serial communication has been modified in these areas:
   a. DMIP – The Digital Mevatron Interface Protocol between the planning systems and the control
   b. MLCIP – The serial communication path between the control console and the 82 Leaf Multi-Leaf Collimator (OPTIFOCUS) utilizing the proprietary MLCIP (MLC Interface Protocol).

(2) The DMIP and MLCIP serial communications design specifications has been used in the previously cleared Siemens Primus (K993425) and ONCOR Avant-Garde with COHERENCE workspace (K031764) Linear Accelerator systems

(3) Setup and delivery of the SIMTEC IM-MAXX 2 (FIMRT) treatment option, utilizing the COHERENCE™ Therapist workspace or the PRIMEVIEW 3i workstation remains the same as for the original SIMTEC IM-MAXX option. The Verify and Record (V & R) systems have been previously cleared i.e. COHERENCE Therapist workspace as part of the ONCOR Avant-Garde (K031764) and the PRIMEVIEW (aka Treatstation, K972275). The current PRIMEVEIW 3i product has a 510(k) non-filing justification on file for the minor, evolutionary changes to the original V & R device. These products have remained unchanged in their intended use.

(4) Fast Intensity Modulated Radiation Therapy (FIMRT) treatment option remains unchanged in the COHERENCE Therapist workspace (for ONCOR systems) and in the PRIMEVIEW3i (for PRIMUS systems) record and verify interface. See Figure 1 Block Diagram, Tab 4.

(5) The safety and control mechanism of system interlocks to stop treatment when the SIMTEC IM-MAXX 2 remains unchanged as for the original SIMTEC IM-MAXX option with one minor addition. An additional assertion of an Error interlock and a new error message has been added.

See the Modified Device Description, Tab 4 and Comparison Table, Tab 5, for the descriptions of these modifications.

General Safety and Effectiveness Concerns:

Labeling: The device labeling contains instructions for use and any necessary caution and/or warnings, to provide for the safe and effective use of the device. The existing device labeling, i.e. User Manual, remains unchanged and has been reviewed as part of the predicate device submissions. A user notification update in the form of a User Release Note will be provided to the user.

Risk Management: Risk management has been assured by use of Risk Analysis, which is used to identify potential hazards. These potential hazards may be controlled or mitigated in part or in combination by several means:

- by a means of design of the application
  - including the refinement of the product requirements and customer requirements
- by software means,
  - including best-practice development, adherence to software configuration control and defect management.
- by documentation means,

- user instructions including device description, use instructions, warnings and/or cautions as necessary.
- by means of testing, including, but not limited to, code review, verification of requirements and validation of user needs and the intended use of the device.
- by means of customer on-site training for the safe and effective use of the device.

Design Control:

The Project Development Procedure (GPA02) contains a provision for tailoring smaller projects utilizing a Design Change Specification (DCS) document which contains sections for project planning for design control, design input, risk management, design output verification and validation testing, reporting testing outcomes and design reviews. Refer to Tab 12.

Intended Use:

The intended use of the PRIMUS and ONCOR Avant-Garde linear accelerator systems is to deliver x-ray radiation for the therapeutic treatment of cancer.

The SIMTEC IM-MAXX 2, software application is an optional software accessory to these devices and is indicated where a specific method of treatment delivery, commercially marketed as Fast Intensity Modulated Radiation Therapy (FIMRT), is desired.

Conclusion:

In conclusion, Siemens is of the opinion that the SIMTEC IM-MAXX 2 option does not introduce any new potential safety risks, has the same intended use, similar technical characteristics and is substantially equivalent to the SIMTEC IM-MAXX option on the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrat
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2005

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

Re: K052315
Trade/Device Name: SIMTEC IM-MAXX 2 Option
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LNH
Dated: August 23, 2005
Received: August 25, 2005

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

TAB 3

510(k) Number (if known): K052315

Device Name: SIMTEC IM-MAXX 2 Option

Indications for Use:

The intended use of the PRIMUS and ONCOR Avant-Garde linear accelerator systems is to deliver x-ray radiation for the therapeutic treatment of cancer.

The SIMTEC IM-MAXX, software application is an optional software accessory to these devices and is indicated where a specific method of treatment delivery, commercially marketed as Fast Intensity Modulated Radiation Therapy (FIMRT), is prescribed by a licensed medical oncologist.

The SIMTEC IM-MAXX 2 software option is intended to further enhance the speed of delivery of the Fast Intensity Modulated Radiation Therapy (FIMRT) treatment delivery technique. The indications for use of this accessory has remained unchanged as a result of the modification.

(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. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052315