SEP 1 4 2005

K052345

GE Healthcare

Advantage Sim MD
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**

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Date Prepared: May 10, 2005

2. **Identification of Product:**

Device name	Advantage Sim MD.
Classification name	Radiation therapy simulation system per 21CFR Section 892 5840
Manufacturer/ Distributor	General Electric Medical Systems 283, Rue de la Minière 78533 BUC Cedex France

3. **Marketed Devices**

Advantage Sim MD is substantially equivalent to the devices listed below:

Model:	Advantage Sim 6.0
Manufacturer:	General Electric Medical Systems
510 (k):	K021780
Model:	Advantage 4D option
Manufacturer:	General Electric Medical Systems
510 (k):	K032915
Model:	Advantage Windows CT/PET Fusion
Manufacturer:	General Electric Medical Systems
510 (k):	K010336

Model:	Volume Viewer Plus
Manufacturer:	General Electric Medical Systems
510 (k):	K041521

4. **Device Description :**

AdvantageSim MD is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning. Anatomical volumes can be defined automatically or manually in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. Definition of the anatomical volumes may be assisted by additional CT, MR, PET or SPECT studies that have been co-registered with the planning CT scan. Additionally, CT & PET data from a respiratory tracked examination may be used to allow the user define the target or treatment volume over a defined range of the respiratory cycle.
The geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage. Defined anatomical structures and geometric treatments fields are displayed on transverse images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the images, or on a beam eye's view display with or without the display of defined structures with or without the display of digitally reconstructed radiograph.

The GE Advantage Sim MD has to ensure relations with the following external systems:

Data Export
Image, volume and plan data are exported in accordance with DICOM V3.0 with all radiotherapy specific data included in a DICOM V3.0 object - including RT Plan and RTSS- Structure Set. Implementation profile is available on request.
NOTE: Any treatment planning system connected to AdvantageSim MD must be DICOM 3.0 compatible and capable of reading the AdvantageSim MD radiotherapy DICOM V3.0 -including RT Plan and RTSS- object Structure Set. Export of treatment plan data to any external system, and its correct interpretation by that system must be fully validated before use.

Marking Systems
AdvantageSim MD stores isocenter coordinates and user defined marker coordinates onto an external accessible directory using a published protocol readable by external mobile laser controller. Currently supports Gammex and LAP formats.
Laser shifts sent to the external laser systems can be corrected for table deflection by identifying the fiducial landmark location within the image volume.

RT Data Import

Image, volume and plan data can be imported in accordance with the RT objects of the DICOM Standard. Import of treatment plan data from an external system, and its correct interpretation by AdvantageSim MD , must be validated before use.

Hardcopy

Hardcopy of all displays and plan data can be made at selected magnification on paper or transparency material. Users can print DRR to film at user defined SID if equipped with an Advantage WorkstationTM compatible Laser camera**, with the appropriate AW Laser Camera Interface. (AW Option). Hardcopy of beam parameters and of isocenter coordinates, using IEC standard, can be made on an optional Postscript printer

Archiving
AdvantageSim MD can save DICOM images and DICOM RT objects on single-session DICOM CD R using an optional CD ROM writer.

Configuration Requirements

AdvantageSim MD is compatible with Advantage Windows WorkstationTM 4.1 or higher

5. **Indications for Use**

Advantage Sim MD is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning. Anatomical volumes can be defined automatically or manually in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. Definition of the anatomical volumes may be assisted by additional CT, MR, PET or SPECT studies that have been co-registered with the planning CT scan. Additionally, CT & PET data from a respiratory tracked examination may be used to allow the user define the target or treatment volume over a defined range of the respiratory cycle.

The geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage. Defined anatomical structures and geometric treatments fields are displayed on transverse images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the images, or on a beam eye's view display with or without the display of defined structures with or without the display of digitally reconstructed radiograph

6. **Comparison with Predicate Device**

Advantage Sim MD, and all of its predicates are software options that operate on Advantage Workstation 4.2 (some predicates on 4.0 and 4.1 as well). The functional features of Advantage Sim MD software package are substantially equivalent to that of the following devices:

Device Name	FDA Clearance Number
Advantage Sim 6.0	K021780
Advantage 4D option	K032915
Advantage Windows CT/PET Fusion	K010336
Volume Viewer Plus	K041521

7. **Adverse Effects on Health**
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:
   - Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
   - Adherence to industry and international standards.

8. **Conclusions**

The Advantage Sim MD does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advantage Sim MD to be equivalent to those of Advantage Sim 6.0 (K021780), Advantage 4D option, Advantage Windows CT/PET Fusion (K010336) and Volume Viewer Plus (K041521).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 18 2012

GE Healthcare
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052345
Trade/Device Name: Advantage SIM MD
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: KPQ
Dated: August 22, 2005
Received: August 26, 2005

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of September 14, 2005,

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 (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); 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,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K052345

Device Name: **ADVANTAGE SIM MD**

Indications for Use:

AdvantageSim MD is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning. Anatomical volumes can be defined automatically or manually in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. Definition of the anatomical volumes may be assisted by additional CT, MR, PET or SPECT studies that have been co-registered with the planning CT scan. Additionally, CT & PET data from a respiratory tracked examination may be used to allow the user to define the target or treatment volume over a defined range of the respiratory cycle.

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Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052345