

MAR 14 2014

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GE Healthcare  
AdvantageSim™ MD with MR pelvic organ at risk segmentation Option  
510(k) Premarket Notification Submission

### 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 16, 2013
Submitter:	GE Hungary Kft. Akron utca 2 2040 Budörs, Hungary
Primary Contact Person:	Angelique Cruz Regulatory Affairs Leader Tel: 0033 (0)1 30 70 47 55 Fax: (262)364-2506
Secondary Contact Person:	Huy Doan Regulatory Affairs Director Tel: 262-312-7751 Mobile: 414-5818553 Fax: : (262)364-2506  Helen Peng Regulatory Affairs Manager Tel: (262)5485091 Fax: (262)364-2506
Device Trade Name:	AdvantageSim™ MD MR pelvic organ at risk segmentation
Common/Usual Name:	AdvantageSim™ MD MR pelvic organ at risk segmentation
Classification Names: Product Code:	21CFR 892.5840, Radiology KPQ
Predicate Device(s):	K132045 - AdvantageSim™ MD with CT Atlas-based Contouring and Replanning Options from GE Healthcare K111311 Segasist Prostate Auto-Contouring Software from Segasist Technologies
Device Description / Intended Use:	AdvantageSim™ MD is a CT/MR/PET oncology application used by clinicians (radiologist, radiation oncologist, medical oncologist,



	<p>nuclear medicine physicians and trained healthcare professional) to assist treatment planning.</p> <p>AdvantageSim MD with MR pelvic organ at risk segmentation Option is used to provide MR based prostate and pelvic organs-at-risk segmentation. A suite of semi-automated MR based organ segmentation contouring allows generating complex structures around organs at risk. These contours overlay on the co-registered CT planning image.</p> <p>The segmentation methods in the modified device are semi-automatic. The user has to place seed points to identify an inner point of the organ to contour.</p> <p>The software offers a suite of manual contour editing tools enabling the user to edit, modify, or change contours generated from the MR segmentation tools to their desired configuration based on their medical and clinical knowledge and experience. The results provided by the software needs to be approved by the experienced clinician and can always be modified or corrected by him/her. It is up to the expert user to accept the result without any change, reject it completely and delineate manually, or modify the result and then save it. The software does not provide any auto-detection or auto-saving functionalities.</p> <p>Same as the predicate devices, the clinician retains the ultimate responsibility for making the pertinent diagnosis and patient management decisions based on their standard practices and visual comparison of the individual images, regardless of the accuracy of the output generated by the software.</p>
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<p>Indications for Use:</p>	<p>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.</p> <p>Definition of the anatomical volumes may be assisted by additional CT, MR or PET studies that have been co-registered with the planning CT scan. Additionally, CT &amp; 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.</p> <p>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.</p>
<p>Technology:</p>	<p>The AdvantageSim MD with MR pelvic organ at risk segmentation Option software employs the same fundamental scientific technology as that of its predicate devices.</p>
<p>Determination of Substantial Equivalence:</p>	<p><u>Summary of Non-Clinical Tests:</u></p> <p>The AdvantageSim MD MR pelvic organ at risk segmentation Option software complies with voluntary standards as detailed in Section 9, 11 and 16 of this premarket submission. The following quality assurance measures were applied to the development of the system:</p> <ul style="list-style-type: none"> <li>▪ Risk Analysis</li> <li>▪ Requirements Reviews</li> <li>▪ Design Reviews</li> <li>▪ Integration testing (System verification)</li> <li>▪ Performance testing (Bench testing, verification)</li> <li>▪ Safety testing (Verification)</li> </ul> <p><u>Summary of Clinical Tests:</u></p> <p>A usability study using consented clinical images was conducted by three board certified Radiation Oncologists who were considered experts. The study was meant to assess the following:</p>

	<ul style="list-style-type: none"><li>• Accuracy of measurement</li><li>• Precision of the measurement</li><li>• Efficiency, as a comparison of amount of time</li><li>• General user Qualitative feedback</li></ul> <p>The study results demonstrated that when used by qualified clinician the new software device has the potential to reduce inter-operator variability , provides statistically significant and practically meaningful clinical efficiency improvements and substantiates the characteristics of this feature, among others, as easy to learn, useful, efficient and providing increased throughput.</p>
Conclusion:	GE Healthcare considers the AdvantageSim MD with MR pelvic organ at risk segmentation Option software application to be as safe, as effective, and performance is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

GE Hungary Kft.  
% Mr. Stephen Slavens  
Regulatory Affairs Director  
GE Medical Systems, LLC  
dba GE Healthcare  
3000 N Grandview  
WAUKESHA WI 53188

March 14, 2014

Re: K132944

Trade/Device Name: AdvantageSim™ MD MR pelvic organ at risk segmentation Option  
Regulation Number: 21 CFR 892.5840  
Regulation Name: Radiation therapy simulation system  
Regulatory Class: II  
Product Code: KPQ  
Dated: January 20, 2014  
Received: January 22, 2014

Dear Mr. Slavens:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

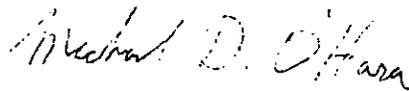
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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>. 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

Enclosure

## Indications for Use

510(k) Number (if known): K132944

**Device Name: AdvantageSim™ MD with MR pelvic organ at risk segmentation Option**

### 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 or PET 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 3D 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.

Prescription Use  \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

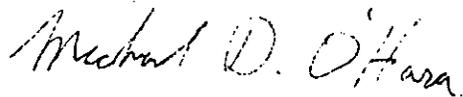
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of Center for Devices and Radiological Health (CDRH)



(Division Sign-Off)

Division of Radiological Health  
Office of In Vitro Diagnostics and Radiological Health  
510(k)        K132944       

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