## 510(k) Summary

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

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| Date: | June 25, 2013 |
| Submitter: | GE Hungary Kft.<br>Akron utca 2<br>2040 Budörs, Hungary |
| Primary Contact Person: | Peter Uhlir<br>Regulatory Affairs Leader<br>Tel: 00 36 23 410121<br>Fax: (262) 364 2506 |
| Secondary Contact Person: | Stephen G. Slavens, RAC<br>Regulatory Affairs Director<br>GE Healthcare<br>Tel: (262) 548 4992<br>Fax: (262) 364 2506 |
| Device Trade Name: | AdvantageSim™ MD with CT Atlas-based Contouring and Re-planning Options |
| Common/Usual Name: | AdvantageSim™ MD with CT Atlas-based Contouring and Re-planning Options |
| Classification Names:<br>Product Code: | 21CFR 892.5840, Radiology<br>KPQ |
| Predicate Device(s): | K052345 - AdvantageSim™ MD<br>K130393 – RTx (Mirada Medical Ltd. LLC) |
| Device Description / Intended Use: | AdvantageSim™ MD is a CT/MR/PET oncology application used by clinicians (radiologist, radiation oncologist, medical oncologist, nuclear medicine physicians and trained healthcare professional) to assist treatment planning. |
| 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. |

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| | 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.<br><br>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. |
| Technology: | The AdvantageSim MD with CT Atlas-based Contouring and Re-planning Options software employs the same fundamental scientific technology as that of the AdvantageSim MD on its predicate devices. |
| Determination of Substantial Equivalence: | Summary of Non-Clinical Tests:<br><br>The AdvantageSim MD with CT Atlas-based Contouring and Re-planning Options 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:<br>▪ Risk Analysis<br>▪ Requirements Reviews<br>▪ Design Reviews<br>▪ Integration testing (System verification)<br>▪ Performance testing (Bench testing, verification)<br>▪ Safety testing (Verification)<br><br>Summary of Clinical Tests:<br><br>The subject of this premarket submission, AdvantageSim MD with CT Atlas-based Contouring and Re-planning Options software did not require clinical studies to support substantial equivalence since the two new features have triggered this 510(k) notification, CT atlas-based contouring and CT based re-planning options are part of Mirada's FDA cleared product. |
| Conclusion: | GE Healthcare considers the AdvantageSim MD with CT Atlas-based Contouring and Re-planning Options 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 – dba GE Healthcare
3000 N. Grandview Blvd.
WAUKESHA WI 53188

September 4, 2013

Re: K132045
Trade/Device Name: AdvantageSim™ MD with CT Atlas-based Contouring and Replanning Options
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: KPQ
Dated: June 25, 2013
Received: July 5, 2013

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): K132045

Device Name: AdvantageSim™ MD with CT Atlas-based Contouring and Replanning Options

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 ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132045