K100552

5. 510(k) Summary

5.1 510(k) owner

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MAR 12 2010

5.2 Contact person

Anders Murman

5.3 Preparation date

12/11/2009

5.4 Trade name

RayStation

RayStation is the product name RaySearch will use introducing this device into the world market. Aliases may be added later, if RayStation is sublicensed to other radiation therapy companies. Throughout the documentation it is our practice to write the trade name and version number together, i.e. "RayStation 1.0".

5.5 Common name

Radiation treatment planning system

5.6 Classification name

Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code MUJ)

5.7 Predicate devices

RayAutoplan 1.0	510(k) number K083264
Oncentra MasterPlan 3.1	510(k) number K081281

5.8 Device description

RayStation is a treatment planning system, i.e. a software program for planning and analysis of radiation therapy plans. Typically, a treatment plan is created by importing patient images obtained from a CT scanner, defining regions of interest either manually or semi-automatically, deciding on a treatment setup and objectives, optimizing the treatment parameters, comparing rival plans to find the best compromise, computing the clinical dose distribution, approving the plan and exporting it.

The main workflow, creating a step-and-shoot IMRT plan from an imported patient and case, is described below:

Flow of Events

User	*System*
1. The user launches RayStation 1.0	
2. The user imports a patient and case with CT images through DICOM	
	3. The system imports the data and checks consistency of in-data
4. The user enters the Structure Definition module and creates ROIs using the contouring tools	
	5. The system adds the ROIs to the patient case
6. The user enters the Treatment Specification module and creates a plan	

and a treatment setup with specified machine, treatment energy and delivery type (SMLC) 7. The user specifies beam configuration including isocenter, dose grid and fluence grid resolution	
	8. The system adds the plan and treatment setup to the patient case
9. The user enters the Plan Optimization module and creates an optimization problem 10. The user defines the algorithm and segmentation settings and starts the optimization	
	11. The system generates a deliverable step-and-shoot plan 12. The system displays the plan as - 2D and 3D dose and patient displays - DVH curves - Plan data (beams, segments etc.)
13. The user reviews the plan 14. The user enters the Plan Evaluation module and evaluates the plan 15. The user approves and exports the plan together with dose, structure sets and images	
	16. The system exports the plan and patient data to a DICOM server

5.9 Intended use

RayStation is a software system designed for treatment planning and analysis of radiation therapy.
The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.
The system functionality can be configured based on user needs.
The intended users of RayStation shall be clinically qualified radiation therapy staff trained in using the system.

5.10 Technological characteristics summary

The technological characteristics are the same for RayStation 1.0 as for RayAutoplan 1.0 and Oncentra MasterPlan v3.1. All devices produce IMRT treatment plans with corresponding dose distributions computed using a three dimensional collapsed cone dose engine. All devices have a function of electronic approval of treatment plans by trained and authorized staff, and export in DICOM format for commencing treatment or archiving.

5.11 Assessment of non-clinical performance data

The dose algorithm in both RayStation 1.0 and RayAutoplan 1.0 is the same. This is supported by the dose algorithm accuracy testing, which has used the same test specification for RayStation 1.0 as was previously used for RayAutoplan 1.0. The tests include dose calculation for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings. All tests were run successfully for RayStation 1.0.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 12 2010

RaySearch Laboratories AB
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

Re: K100552
Trade/Device Name: RayStation
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: February 19, 2010
Received: February 26, 2010

Dear Mr. Conry:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100552

Device Name: RayStation

Indications for Use:

RayStation is a software system designed for treatment planning and analysis of radiation therapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

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Prescription Use ___YES___ 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)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100552