RaySearch Laboratories

5. 510(k) Summary

5.1 510(k) owner

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5.2 Contact person

David Hedfors, Quality and Regulatory Affairs Manager

5.3 Preparation date

02/03/2012

5.4 Trade name

RayStation

RayStation is the product name RaySearch will use introducing this device into the world market. Throughout the documentation it is our practice to write the trade name and version number together, i.e. "RayStation 2.5" to easily distinguish from the predicate device 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

RayStation 1.0 K100552

IPLAN RT K103246

5.8 Device description

RayStation 2.5 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 2.5	
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.

The intended use for RayStation 2.5 is the same as for the predicate device RayStation 1.0.

5.10 Technological characteristics summary

The technological characteristics are the same for RayStation 2.5 as for the predicate device RayStation 1.0.

Comparing version 1.0 with version 2.5, the new version includes usability, performance and connectivity improvements. Both versions are built on the same software platform and share basic design. Both versions have been developed under the same quality system meeting the same requirements for safety and effectiveness.

The RayStation 2.5 dose tracking technology is substantially equivalent to the predicate device IPLAN RT dose tracking.

In RayStation it is possible to evaluate a treatment during the treatment course. Similar to IPLAN RT, marketed under the name iPlan© for Adaptive Radiotherapy by BrainLAB, daily images such as Cone Beam CT (CBCT) can be imported and rigidly registered with the treatment planning CT according to positioning in the treatment room.

Following a similar workflow as iPlan©, the CBCT can be segmented using Model Based Segmentation or, after correlating the CBCT to the 3D space of the planning CT through deformable registration, contours defined on the planning CT can be automatically transferred to the CBCT. Delivered dose can be computed on the CBCT. This allows for an evaluation of volumetric changes, dose coverage changes in comparison with the planned dose and for accumulated dose analysis.

5.11 Assessment of non-clinical performance data

The test specification of RayStation 2.5 is a further developed version of the test specification of RayStation 1.0. This is supported by the requirements specification, for which the same is true. The successful verification and validation of RayStation 2.5 therefore support the substantial equivalence of the two RayStation versions.

The verification performed for dose tracking verifies the functionality for

- computing dose on CBCT
- deforming a fraction dose to the planning image given an approved deformable registration
- comparing planned dose, delivered dose and accumulated dose on planned or fraction images

The test results verify the requirements for dose tracking and thereby support a determination of substantial equivalence.

5.12 Test conclusion

The summary of the performed non-clinical tests shows that RayStation 2.5 is as safe and effective, and performs as well as the predicate devices.

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

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APR - 6 2012

Re: K120387
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 7, 2012
Received: February 7, 2012

Dear Mr. Hedfors:

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number:

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.

The intended users of RayStation shall be clinically qualified radiation therapy staff trained in using the system.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 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
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120387

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