RaySearch Laboratories AB (publ)
% Ms. Viktoria Hammarstedt
Quality and Regulatory Affairs Specialist
Sveavägen 44
Stockholm, 11134
SWEDEN

September 24, 2020

Re: K200569
Trade/Device Name: RayStation 9.1 / RayStation 9.2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: June 11, 2020
Received: August 26, 2020

Dear Ms. Hammarstedt:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200569

Device Name
RayStation 9.1 / RayStation 9.2

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary

5.1 510(k) owner

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5.2 Contact person

Viktoria Hammarstedt
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5.3 Preparation date

February 19, 2020

5.4 Trade name

The trade name is RayStation.

The trade name and version number are written together, i.e. “RayStation 9.1/RayStation 9.2” to easily distinguish the submitted device from the predicate device RayStation 8.1.

The marketing name is RayStation 9B and 9B SP1.

5.5 Common name

Radiation therapy treatment planning system

5.6 Classification name

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

5.7 Predicate device

RayStation 8.1 K190387

5.8 Device description

RayStation 9.1/RayStation 9.2 are radiation therapy treatment planning systems, i.e. a software program for planning and analysis of radiation therapy. The functionality includes fusion capabilities (CT, PET and MRI), contouring, collapsed cone convolution dose computation, 4D data compatibility and treatment console interfacing, as well as unique features such as machine learning planning and segmentation, multi-criteria optimization, dose tracking, treatment adaptation and deformable registration, all available in one platform.

The main workflow, creating a treatment plan from imported patient image data, is described below:

Flow of Events

	User		***System***
1.	The user launches RayStation 9.1/RayStation 9.2		
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 Plan Setup module and		

creates a plan and a treatment setup with specified machine, treatment energy and delivery type	
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 optimizes the plan parameters	
	10. The system generates a deliverable plan 11. The system displays the plan as - 2D and 3D dose and patient displays - DVH curves - Plan data (beams, segments etc.)
12. The user reviews the plan 13. The user enters the Plan Evaluation module and evaluates the plan 14. The user approves and exports the plan together with dose, structure sets and images	
	15. 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 9.1/RayStation 9.2 as for the predicate device RayStation 8.1.

Comparing RayStation 9.1/RayStation 9.2 with RayStation 8.1, the newer version includes usability improvements as well as dose calculation based on dual-energy CT/SRS image data, updates to accommodate updated Toshiba beam intensity calculations, and support for seated treatments. Both versions are built on the same software platform and share design to a high degree. Both versions have been developed under the same quality system meeting the same requirements for safety and effectiveness.

5.11 Assessment of non-clinical performance data

The test specifications of RayStation 9.1/RayStation 9.2 are further developed versions of the test specifications of RayStation 8.1. This is supported by the requirements specification, for which the same is true. The successful verification and validation of RayStation 9.1/RayStation 9.2 therefore support the substantial equivalence of the above RayStation versions.

5.12 Test conclusion

The summary of the performed non-clinical tests shows that RayStation 9.1/RayStation 9.2 are as safe and effective and performs as well as the predicate device.