December 22, 2025

RaySearch Laboratories AB (publ)
Olympiada Lachana
QA/RA Specialist
Eugeniavägen 18C
Stockholm, 11368
Sweden

Re: K252109
Trade/Device Name: RayStation (2024A SP3)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: July 4, 2025
Received: July 7, 2025

Dear Olympiada Lachana:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252109

Please provide the device trade name(s).

RayStation (2024A SP3)

Please provide your Indications for Use below.

RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

Please select the types of uses (select one or both, as applicable).

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

K252109 510(K) SUMMARY (21 CFR § 807.92)

I. Contact Details

Applicant

RaySearch Laboratories AB (publ)

Eugeniavägen 18C Stockholm 113 68 Sweden
+46 8 510 53000

Contact

Ms. Olympiada Lachana
quality@raysearchlabs.com

Preparation Date

7 August, 2025

II. Device

Device Trade Name

Device Name	Software Version number
RayStation	2024A SP3

Common Name

Medical charged-particle radiation therapy system

Classification Name

System, Planning, Radiation Therapy Treatment

Regulation Number

892.5050

Product Code(s)

MUJ

III. Legally Marketed Predicate Device

Predicate
K240398

Predicate Trade Name
RayStation 2024A SP3

Product Code
MUJ

Reference Device used: RayStation 11B, K220141.

Use of reference device: The RayTreat application was previously cleared with RayStation 11B, K220141. Since then, some RayTreat functions have been changed compared with RayStation 11B and therefore the use of RayStation 11B as a reference device is essential to compare and describe the changes.

IV. Device Description Summary

Explanation of how the device functions

RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

RayStation consists of multiple applications:

- The main RayStation application is used for treatment planning.
- The RayPhysics application is used for commissioning of treatment machines to make them available for treatment planning and used for commissioning of imaging systems.
- The RayTreat application is used for sending plans to treatment delivery devices for treatment and receiving records of performed treatments.

The device to be marketed, RayStation 2024A SP3, adds the RayTreat application compared with last cleared version, the predicate RayStation 2024A SP3 (without RayTreat), K240398.

The RayTreat application was previously cleared with RayStation 11B, K220141. Since then some RayTreat functions have been changed:

- RayTreat is now session focused
- Usability improvements
- Bug fixes

Device design information

The RayStation applications are built on a software platform, containing the radiotherapy domain model and providing GUI, optimization, dose calculation and storage services. The platform uses three Microsoft SQL databases for persistent storage of the patient, machine and clinic settings data.

As a treatment planning system, RayStation aims to be an extensive software toolbox for generating and evaluating various types of radiotherapy treatment plans. RayStation supports a wide variety of radiotherapy treatment techniques and features an extensive range of tools for manual or semi-automatic treatment planning.

The RayStation applications are divided into modules, which are activated through licensing.

The RayTreat application

RayTreat manages treatment delivery. An approved plan can be assigned to fractions in a treatment course and sent to the treatment delivery device. Treatment records from the treatment delivery device are recorded and sent to RayCarePACS.

Note that all real-time monitoring of actual delivery is handled by treatment delivery device software, not by RayStation.

Scientific concepts that form the basis for the device and significant performance characteristics:

RayStation is a stand-alone software medical device intended for radiation therapy. Input to the device is patient, disease and treatment unit information, output from the device is one or more treatment plans. The treatment plans include treatment unit parameter settings for optimal beam arrangements, energies, field sizes, and ultimately fluence patterns to produce as safe and effective radiation dose distribution as the predicate.

The scientific concepts of a treatment planning system are patient and beam modeling, and algorithms for dose calculation and plan parameter optimization.

The patient model is a computerized representation of the patient tissue and densities, identifying the target regions and particular organs at risk. The model is based on medical images of the patient and must have the desired level of accuracy. Likewise, the beam modeling is a computerized representation of the treatment unit, defined by fluence type, energy distribution, machine specific geometry, and beam modifiers such as MLC, flattening filters, wedges etc. The algorithms for dose calculation and plan parameter optimization must take into account all geometries and materials that affect irradiation transport through the treatment unit and the patient. The optimization algorithm iterates treatment plan parameters until the desired treatment plan and dose distribution have been obtained. Also here, all steps must be done to the desired level of accuracy.

Significant physical characteristics of the device, material used, and physical properties:

The device is a standalone software medical device. It has no physical properties or materials. The device design information can be found in the subsection above “Device design information”.

V. Intended Use/Indications for Use

RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

Indications for Use Comparison

The indications for use are the same as for the predicate device.

VI. Technological Comparison

Comparing RayStation 2024A SP3 with RayTreat with the previously cleared RayStation 2024A SP3 without RayTreat, both devices are treatment planning systems. Based on user input, both RayStation versions propose treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, both RayStation versions may also be used to administer treatments.

General **function**s comparison table

Item	Compared to RayStation 2024A SP3	Comment
Hardware platform	Substantially Equivalent	RayStation 2024A SP3 (with RayTreat) and RayStation 2024A SP3 all use standard office PCs as hardware platform.
Operating system	Substantially Equivalent	RayStation 2024A SP3 (with RayTreat) and RayStation 2024A SP3 all use Windows 10 Professional (or higher) and Windows Server 2012 R2 (or higher). See RayStation 2024A System Environment Guidelines for details.
Target population	Substantially Equivalent	RayStation 2024A SP3 (with RayTreat) and RayStation 2024A SP3 are intended for the same target population and anatomical sites; persons that have been prescribed an external beam radiation therapy or chemotherapy treatment.
Anatomical sites	Substantially Equivalent	
Human factors	Substantially Equivalent	In terms of human factors, the systems are considered equivalent. There are minor changes only. The user interfaces use the same framework with the same controls and views.
Standards met	Substantially Equivalent	RayStation 2024A SP3 (with RayTreat) and RayStation 2024A SP3 all comply with the IEC 61217, IEC 62083, IEC 62304, IEC 62366-1 and ISO 14971.
Image types	Substantially Equivalent	RayStation 2024A SP3 (with RayTreat) and RayStation 2024A SP3 all support CT, PET and MR images for identifying patient organs and contouring.
Reporting aspects	Substantially Equivalent	When evaluating and approving treatment plans, all necessary data is presented to the user and available in print in all systems.

Item	Compared to RayStation 2024A SP3	Comment
Image storing	Substantially Equivalent	None of the systems are intended for long term storage of images or other patient data.
Network / remote connections and capabilities	Substantially Equivalent	All systems are capable of network transfer of patient data using the DICOM protocol RayStation 2024A SP3 (with RayTreat) and RayStation 2024A SP3 are designed for desktop use and for remote access using standard virtualization techniques. Remote connection to the system is verified in detail and equivalent to local connection.
Cybersecurity	Substantially Equivalent	No architectural changes or major new functions that affect cyber security.

The above listed changes in the general functions do not raise different questions of safety or effectiveness.

The changes in the device to be marketed are the following:

I. The RayTreat application is added in the device to be marketed, compared with the predicate device, RayStation 2024A SP3. However, the RayTreat application was previously cleared with the reference device RayStation version 11B, K220141.

II. The device to be marketed also contains a validation for Hyperscan plans with Boron Carbide energy selector plates. This change is an additional validation and results in no changes in the technological characteristics of the device compared to the predicate device, RayStation 2024A SP3.

The principle of operation of the device to be marketed is the same as that of the existing predicate device. Verification and validation demonstrate that the device to be marketed is as safe and effective as the predicate. RaySearch therefore believes that the device to be marketed is substantially equivalent to the predicate device.

The RayTreat application contains some new and modified functions which are compared to the RayTreat application in the reference device RayStation 11B and presented in the table below.

Changed RayTreat function in RayStation 2024A SP3 (with RayTreat) compared to reference device, RayStation 11B	Description of the RayTreat function changes	Evaluation of change compared to RayStation 11B, K220141
Bug fixes, not recall associated.	Bugs have been resolved related to stuck sessions, evaluation licenses, continuation sessions, nominal progress, import of treatment records, changing patient/room name, updates of beam sets, approval of alternative plans. Also bug fixes related to the communication with Radixact® have been resolved.	Substantially Equivalent. The function change does not raise different questions of safety or effectiveness.
Bug fix related to recall RES 90498/FSN 99333.	Recall bug has been resolved related to treatment course information not being synced with RayCare.	Substantially Equivalent. The function change does not raise different questions of safety or effectiveness.

Changed RayTreat function in RayStation 2024A SP3 (with RayTreat) compared to reference device, RayStation 11B	Description of the RayTreat function changes	Evaluation of change compared to RayStation 11B, K220141
RayTreat is now session focused.	Treatment course information is no longer displayed in RayTreat results workspace, it is displayed in RayCare.	Substantially Equivalent. The function change does not raise different questions of safety or effectiveness.
Usability improvements.	Usability improvements in: • Room and activity status • Scheduling workspace • Preparation workspace • Results workspace	Substantially Equivalent. The function change does not raise different questions of safety or effectiveness.

VII. Non-Clinical and/or Clinical Tests Summary

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "Major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient.

Cybersecurity and Interoperability requirements were assessed per FDA guidance's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Sept 2023)" as for the predicate. The cybersecurity analysis showed that the cybersecurity risks are mitigated, and the residual risk is acceptable. The devices are secure for use in their intended environment and methods are in place for ensuring security throughout the total product lifecycle.

Compliance with device-specific recognized consensus standards, along with general and collateral safety and performance standards for medical devices listed below, ensures that basic safety and essential performance requirements are met.

Standards applied:

Standard No.	Standard Title	Recognition no.
IEC 61217	Radiotherapy equipment - Coordinates movements and scales	12-267
IEC 62304	Medical device software - Software life cycle processes	13-79
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
ISO 14971	Medical devices - Application of risk management to medical devices	5-125
IEC 62083	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	12-217
IEC 81001-5-1	Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle	13-122

According to the FDA's "General Principles of Software Validation", software verification provides evidence that design outputs meet specified requirements for each development phase. Software validation confirms that software specifications meet user needs and intended uses, ensuring consistent fulfillment of requirements.

Below is an overview of the verification and validation activities used to demonstrate substantial equivalence. The specific validation activities for selected significant functions are presented in the table below.

- **Unit Testing**: This involves testing individual software requirements to ensure that small sections of the code function as intended in isolation. It helps identify and fix bugs at an early stage.
- **Interoperability Testing:** This type of testing ensures that software and hardware components can exchange information and use the information that has been exchanged effectively. It verifies that the software and the treatment machine can work together seamlessly.
- **System Level Testing**: This testing evaluates the entire software system to ensure it meets the specified requirements to validate the overall behaviour of the system.
- **Cybersecurity Testing**: This testing assesses the software's ability to protect against cyber threats and vulnerabilities. It includes penetration testing to ensure the software is secure and resilient against attacks.
- **Regression Testing**: This testing ensures that changes to the software do not introduce new bugs or negatively impact existing functionality. It involves re-running previously conducted tests to verify that the software still performs as expected after changes.

In the below table, an overview of the verification and validation activities is presented for the changes in the device to be marketed, RayStation 2024A SP3 (with RayTreat).

Changed RayStation function in RayStation 2024A SP3 (with RayTreat) compared to predicate device, RayStation 2024A SP3.	**Verification and validation data used to demonstrate substantial equivalence**	**Substantially equivalent?**
Addition of RayTreat application	System level verification and validation and unit tests. Purpose of testing: To verify that RayTreat performs as intended and as in reference device RayStation 11B. No new, unmitigated hazards have been added compared to predicate device RayStation 2024A SP3. For the verification of changes to RayTreat since the last cleared device with RayTreat, RayStation 11B, refer to the following table.	Yes. The successful validation of this function change demonstrates that the device is as safe and effective as the predicate device.

Changed RayStation function in RayStation 2024A SP3 (with RayTreat) compared to predicate device, RayStation 2024A SP3.	Verification and validation data used to demonstrate substantial equivalence	Substantially equivalent?
Additional validation related to Hyperscan plans in RayStation 2024A SP3		**Substantially equivalent?**
Dose engine validation for Hyperscan plans with Boron Carbide energy selector plates	Dose engine validation to validate that RayStation can compute the dose to required accuracy also for Boron Carbide based Mevion Hyperscan systems.	Yes. The successful validation of this function change demonstrates that the device is as safe and effective as the predicate device.

In the below table, an overview of the verification and validation activities is presented for changed RayTreat functions compared to the reference device RayStation 11B.

Changed RayTreat function in RayStation 2024A SP3 (with RayTreat) compared to reference device, RayStation 11B.	Verification and validation data used to demonstrate substantial equivalence	Substantially equivalent?
RayTreat is now session focused	System level verification and validation. Purpose of testing: Perform a main flow and verify that the treatment delivery is successful using: • IBA machine simulator • TomoTherapy TDCS Radixact simulator • CyberKnife simulator Pass criteria: The session (treatment or QA plan) has been completed, and the treatment record has been received in RayCare.	Yes. The successful validation of this function change demonstrates that the device is as safe and effective as the predicate device.
Usability improvements	System level verification and validation. Purpose of testing: • Verify that the Patient card, task list, beam set note and appointment comments details. Pass criterion: The new comment is visible in RayTreat, and the status of the changed appointment is updated. • Verify that Send session to driver although QA has not been performed.	Yes. The successful validation of this function change demonstrates that the device is as safe and effective as the predicate device.

Changed RayTreat function in RayStation 2024A SP3 (with RayTreat) compared to reference device, RayStation 11B.	Verification and validation data used to demonstrate substantial equivalence	Substantially equivalent?
	Pass criteria: In RayTreat, the icon indicating that the session has warnings that need to be overridden shall appear again. It shall not be possible to open the session. • Verify the setting and changing of setup instructions and machine model from RayCare. Pass criterion: The setup instructions used during delivery match what is seen viewing the delivered sessions. • Verify that the treatment delivery is successful using: ○ IBA machine simulator ○ TomoTherapy TDCS Radixact simulator ○ CyberKnife simulator Pass criteria: The session (treatment or QA plan) has been completed and the treatment record has been received in RayCare.	

The data obtained from the verification show that system tests, use error tests, unit and subsystem tests are acceptable, and the validations have been completed successfully. The reviews of design, code and labeling met the acceptance criteria.

From the successful verification and validation activities, the conclusion can be drawn that RayStation 2024A SP3 with RayTreat has met specifications and is as safe, as effective and perform as well as the legally marketed predicate devices.

VIII. Animal Testing

No animal testing was required to demonstrate substantial equivalence.

IX. Clinical Testing

No Clinical trials were required to demonstrate substantial equivalence.

X. Conclusion

The changes between the predicate and device to be marketed do not raise any new or different questions of safety or effectiveness.

In the Technological Comparison section above, the added RayTreat application in RayStation 2024A SP3 is compared to the predicate device, RayStation 2024A SP3 in a General functions comparison table. The changes to RayTreat since the last cleared RayStation version with RayTreat, 11B have been compared in a Changed RayTreat function Table of section VI. All compared items are evaluated as substantially equivalent and do not raise different questions of safety of effectiveness.

The non-clinical data support the safety of the device as compared to the predicate and the software verification and validation demonstrate that the RayStation 2024A SP3 device with RayTreat should perform as intended in the specified use conditions, and the performance testing demonstrates that the RayStation 2024A SP3 device with RayTreat performs as well as the predicate device, RayStation 2024A SP3 that is currently marketed for the same intended use.

Therefore, all the changes are substantially equivalent to the predicate device RayStation 2024A SP3 cleared under K240398.