April 17, 2025

RaySearch Laboratories AB (publ)
Olympiada Lachana
QA/RA Specialist
Eugeniavägen 18C
Stockholm, 113 68
Sweden

Re: K242992
Trade/Device Name: RayCare (2024A SP1)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: September 26, 2024
Received: September 26, 2024

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,

Jennifer A. Segui -S
2025.04.17 17:22:36 -04'00' for

Lora Weidner
Assistant Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242992

Device Name

RayCare (2024A SP1)

Indications for Use *(Describe)*

RayCare is an oncology information system intended to provide information which is used to take decisions for diagnosis, treatment management, treatment planning, scheduling, treatment and follow-up of radiation therapy, medical oncology and surgical oncology.
For these disciplines, as applicable, RayCare enables the user to define the clinical treatment intent, prescribe treatment, specify the detailed course of treatment delivery,manage the treatment course and monitor the treatment course.
In the context of radiation therapy, the RayCare image viewer can be used for viewing images, annotating images, performing and saving image registrations as well as image fusion to enable offline image review of patient positioning during treatment delivery.
RayCare is not intended for use in diagnostic activities.

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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510(K) SUMMARY (21 CFR § 807.92)

I. Contact Details

Applicant
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Contact
Ms. Olympiada Lachana
quality@raysearchlabs.com

Preparation Date
16 April, 2025

II. Device

Device Trade Name
RayCare (2024A SP1)

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

K200487

Predicate Trade Name

RayCare 3B

Product Code

MUJ

IV. Device Description Summary

RayCare is an oncology information system intended to provide information which is used to take decisions for diagnosis, treatment management, treatment planning, scheduling, treatment and follow-up of radiation therapy, medical oncology and surgical oncology.

For these disciplines, as applicable, RayCare enables the user to define the clinical treatment intent, prescribe treatment, specify the detailed course of treatment delivery, manage the treatment course and monitor the treatment course.

In the context of radiation therapy, the RayCare image viewer can be used for viewing images, annotating images, performing and saving image registrations as well as image fusion to enable offline image review of patient positioning during treatment delivery.

As an oncology information system, RayCare supports healthcare professionals in managing cancer care treatments. The system provides functionalities as described briefly in the sections below. These functionalities are not provided separately in different applications and have a joint purpose for the treatment of the patient.

RayCare is a software-as a Medical Device with a client part that allows the user to interact with the system and a server part that performs the necessary processing and storage functions. Selected aspects of RayCare are configurable, such as adapting workflow templates to the specific needs of the clinic.

V. Intended Use/Indications for Use

RayCare is an oncology information system intended to provide information which is used to take decisions for diagnosis, treatment management, treatment planning, scheduling, treatment and follow-up of radiation therapy, medical oncology and surgical oncology.

For these disciplines, as applicable, RayCare enables the user to define the clinical treatment intent, prescribe treatment, specify the detailed course of treatment delivery, manage the treatment course and monitor the treatment course.

In the context of radiation therapy, the RayCare image viewer can be used for viewing images, annotating images, performing and saving image registrations as well as image fusion to enable offline image review of patient positioning during treatment delivery.

RayCare is not intended for use in diagnostic activities.

Indications for Use Comparison

The indications for use are the same as the predicate device. The intended use has been rephrased to better clarify the same indications for use.

VI. Technological Comparison

Comparing RayCare 2024A SP1 with RayCare 3B, both devices are oncology information systems and are used to manage clinical and administrative workflows for treatment planning and delivery. They both support information flow among healthcare facility personnel and can be used whenever radiotherapy is prescribed.

Some software features and characteristics in RayCare 2024A SP1 are different from the predicate device, RayCare 3B. However, these differences are considered by RaySearch to be enhancements of the predicate. The principle of operation of the subject device is the same as that of the existing predicate device. Verification and validation demonstrate that the subject device is as safe and effective as the predicate. RaySearch therefore believes that the subject device is substantially equivalent to the predicate device.

The comparison of the added/updated functions in RayCare 2024A SP1 with functions in the predicate device is presented in the table below.

Added/updated function in RayCare 2024A SP1 compared with predicate device, RayCare 3B	**Description of the RayCare function**	**Compared with RayCare 3B, K200487**
Updated Patient Chart feature	• Family history – Patient Chart feature for documenting family history of the patient. • Implantable device list – Patient Chart feature for documenting and looking up implantable device based on UDI. • Current profile – Patient Chart feature for free text documentation of the patient's status and history. • Social history – Patient Chart feature for documenting aspects of the patient's social history such as living situation and drug/alcohol consumption.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness

	• Notes – Patient Chart feature for documenting non-structured notes about the patient. • Workspace for scripts in Patient Chart. • Radiotherapy prescription - Workspace in RayCare Patient Chart to enter and approve radiotherapy prescriptions. • Configurability of document templates - Extension of the administration workspace for creating and publishing forms which can be used for documenting Patient Chart data. • Prefilled templates for Patient Chart workspaces - System administration workspace for creating and managing Patient Chart template data. • Usability Enhancements for Patient Chart. • Enhancements to the Care management and Clinical Profile parts of Patient Chart. • Minor improvements to workspaces in Patient Chart and task management. • Structured management of setup devices - Administration workspace for managing setup devices and support for adding setup devices to setup instructions in Patient Chart.	
PACS archiving – support for archiving, i.e., moving PACS data to other external PACS	The PACS archiving feature provides support for archiving, i.e., moving PACS data to other external systems capable of receiving DICOM data and making it available to be retrieved again later using RayCare PACS.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
RayCare scripting	RayCare scripting provides support for running python scripts to read and edit selected whitelisted data in RayCare. All such properties are also accessible to the user for read/edit via the user interface.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Task support with task lists in RayStation	Task list with RayCare tasks displayed in RayStation to support managing treatment planning tasks while performing treatment planning in the TPS.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Updated workflow feature	• Parallel workflow support. • Workflow configurability for users: checklists, due dates and task descriptions. • Configurability of workflows and tasks - Administration workspace for configuring workflows, tasks and appointments.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness

Updated whiteboard feature	• New whiteboard for QA planning tasks. • Treatment overview whiteboard – Whiteboard to display patient status for ongoing treatment courses. • Resource overview whiteboard – whiteboard which displays the occupancy of resources at the clinic for the coming weeks. • Reintroduced the treatment whiteboard available in RayCare 6A.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Additional scripting support	• Extended RayCare scripting support. • RayWorld scripts.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Introduction of patient cases, care plans and protocols	The Cases, and care plans and protocols tab located can be managed from the Care administration tab section in Patient Chart. These concepts provide support for organization of patient data.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Extended diagnosis management	The diagnosis management is extended to support ICD-0-3 diagnosis codes and add more structured data about the diagnosis such as topographical code morphological, affected side of the patient as well as diagnostic confirmation.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Management of multiple setups and multiple planning instructions	A new way of computing the dose compensation point was added since the previously exported position was suboptimal. The point is calculated by taking the center of the volume formed of the dose voxels with dose above 90% of the max dose.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Document management improvements	The document management improvements add support for extracting document data from the report database and for opening imported documents in external software selected by the clinic.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Admin UI for management for external integrations	The Integrations workspace in in the System administration part of RayCare allows for editing of settings related to external integrations.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Display of accumulated nominal dose	The nominal progress feature in RayCare displays the accumulated nominal dose based on the beam set prescription of delivered beam sets delivered to RayCare from RayStation.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Radiotherapy treatment history	The Treatment history workspace provides support for documenting previously delivered radiotherapy treatments for the selected patient.	Substantially Equivalent. The feature does not

		raise different questions of safety or effectiveness
Configurable forms - Administration workspace for creating and publishing forms which can be used for documenting Patient Chart data. Workspace in Patient chart where forms can be added for the patient and thereafter filled in and approved.	RayCare Forms is an improvement in the existing documents support in RayCare. Forms can be configured by RayCare system administrators to include items such as data pulled from RayCare, text fields and static texts. The configured document can then be added to the Patient Chart.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Toxicities management workspace	Toxicity information can be added to a toxicity assessment in the Clinical profile part of Patient Chart. The toxicities added in RayCare are used to document toxicities that appear during treatment for a patient. Toxicities are added using a toxicity grading system that is created and managed in the admin workspace in RayCare.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Display of two additional values in RayCare GUI	The possibility to indicate that the patient is pregnant has been added to the Vitals workspace located under the Clinical profile tab section in the Patient Chart. Support to display session warnings from the Varian TrueBeam will display dose limit overrides made on the TrueBeam.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Account management workspace	Account numbers can now be configured in the Charges workspace in the Care administration section in Patient Chart. It is possible to add or edit accounts and to set a default account for a patient.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Enhancements for task management and scheduling	• Improved usability of the user workflow. • GUI improvements. • Enhancements to the Task management. • Enhancements to the Scheduling and Calendar workspace.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Additional support for external interfaces	• Support for importing and exporting treatment course data using external interfaces (inspired by IHE-RO XRTS profile). • Extensions to HL7 interfaces. • External API framework – no functional implications, only framework support for developers to facilitate exposing domain values in external interfaces.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness

	• Outbound HL7/FHIR document interface. • Extended HL7 ADT and inbound document interfaces.	
Treatment course management (new functionality for this product, moved from RayStation product)	The Treatment course management workspace provides the functionality to manage and design a treatment course for a selected care plan and assign plans and other relevant delivery data such as tabletop positions to treatment sessions.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Improved integration mechanism with other RaySearch products (updated functionality)	The improved integration mechanism supplies developer framework support for integrating with other RaySearch products. There are no functional consequences for the software.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Treatment delivery integration framework to support communication between RayCare OIS and treatment devices	Framework for communicating treatment session data such as RT Plan, planning image, setup instructions, treatment- and QA appointments to the software running on a treatment device.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Offline and online recording of treatment results with additional support for importing DICOM treatment records	Offline and online treatment recording supports adding treatment results from a radiotherapy treatment. The recording can be done automatically using treatment records from the treatment device (online) or by uploading treatment records after treatment (offline) or by manually recording the delivered dose.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Treatment delivery interoperability with Varian TrueBeam	Treatment delivery interoperability for the Varian TrueBeam is supported using the treatment delivery integration framework.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
2D-2D offline image review support for Varian TrueBeam	2D-2D offline image review support for Varian TrueBeam adds support for reviewing 2D-2D registrations to the existing Offline image review feature.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Support for scheduling QA sessions	Support for scheduling QA sessions allows the user to schedule QA for a specific beam set in RayCare. It also adds QA appointments to the appointments exposed to treatment devices using the treatment delivery integration framework.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Updated treatment course feature	• Improvements to the treatment course management workspace, adding more approval options. • Improvements to Treatment course overview workspace, adding more information about treatment related data for delivered treatments etc.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness

Support for upgrading the product from RayCare 6A to RayCare 2024A	Database upgrade from RayCare 6A data model to RayCare 2024A data model. The upgrade does not introduce any functionality in the product.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
Updated the online couch corrections table in the Treatment course overview workspace and add/edit delivery results dialog	It is now possible to see the actual position and the applied shift for each delivery record in that session in the same table, ordered at delivery time.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness
General fixes, not recall associated	• Fixes related to scheduling, document management, RayCare TrueBeam integration, character sets used on export from PACS, not recall associated. • Stability improvements. • The default polling frequency for RayStation script progress has been decreased to every 2 seconds.	Substantially Equivalent. The feature does not raise different questions of safety or effectiveness

VII. Non-Clinical and/or Clinical Tests Summary

Nonclinical tests include software verification and validation. Those types of tests, as specified in the Guidance document "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions - Guidance for Industry and Food and Drug Administration Staff (fda.gov)" are excluded from bench performance testing.

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.

Moreover, the cybersecurity analysis showed that the cybersecurity risks are mitigated, and the residual risk is acceptable for RayCare 2024A SP1. The device is secure for use in its intended environment and methods are in place for ensuring security throughout the total product lifecycle.

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

Automated and manual verification activities were created as part of the implementation of product backlog items and performed throughout the project, i.e., continuously during development and during verification and validation preparation and finally during formal verification and validation.

The type of data obtained through software verification is test results from automated and manual test runs. From automated tests, the data type is binary pass or fail result. From manual tests, the type of data is also pass or fail based on manual execution of tests according to specification and comparison of results with the specified expected results.

The purpose of data obtained through verification is to determine successful or failed verification of the requirement linked to the verification activity. The requirement can state e.g. that a certain accuracy must be obtained, a certain input data range is allowed, or that some information must be clearly displayed to the user. The purpose of the verification of the requirements is to verify the consistency, completeness, and correctness of the software and its supporting documentation. The purpose of the verification is also to verify the quality of the source code, correctness of software design, the integration of internal and external components and the correct function of UI components and use cases.

According to the FDA document “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”, software verification “provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase”, and software validation is “confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled”.

Below is an overview of the verification and validation activities used to demonstrate substantial equivalence. The specific validation activities for selected significant features 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.
- **Integration Testing**: This type of testing focuses on verifying that different module of the software work together as intended. It ensures that the integrated system functions correctly.
- **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.
- **Usability Testing**: This testing evaluates the software's user interface and user experience. It involves testing the software with real users to identify usability issues and ensure that the software is as safe as the predicate, easy to use and meets user needs.

- **Regression Testing**: This testing ensures that updates 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 modifications.

In the below table, an overview of the verification and validation activities is presented for selected significant features.

Added/updated function in RayCare 2024A SP1 compared to predicate device, RayCare 3B.	**Verification and validation data used to demonstrate substantial equivalence**	**Substantially equivalent?**
Treatment course management (new functionality for this product, moved from RayStation product)	Methodology: System level verification and validation to verify that the Treatment course management (TC management/TCM) workspace provided the functionality to manage and design a treatment course for a selected care plan and assign plans and other relevant delivery data such as tabletop positions to treatment sessions. Purpose: The TCM workspace shall show the treatment course and its related series, treatment fractions and assigned beam sets for the care plan selected in the global care plan selector. Pass criteria: • The treatment series related to the selected care plan is displayed. • The fractions in the fractions table are only related to the treatment series related to the selected care plan. • The assigned beam set table only displays the beam set related to the selected care plan.	Yes. The successful validation of this feature demonstrates that the device is as safe and effective as the predicate device.
Extended RayCare scripting support	Methodology: Unit testing and system level verification and validation to verify that RayCare scripting provides support for running python scripts to read and edit selected whitelisted data in RayCare. Purpose of unit testing: Verify that only whitelisted data is available for scripting. Criterion in unit testing: • The queries shall only be available for scripting if explicitly declared as scriptable Purpose of system level verification: Verify that it is possible to run a script by clicking a RayCare script task.	Yes. The successful validation of this feature demonstrates that the device is as safe and effective as the predicate device

Added/updated function in RayCare 2024A SP1 compared to predicate device, RayCare 3B.	Verification and validation data used to demonstrate substantial equivalence	Substantially equivalent?
	Criterion in system level verification: • Verify that the script has performed the expected action within RayCare.	
Offline and online recording of treatment results. Support for importing DICOM treatment records in case a treatment performed with RayCare failed	Methodology: System level verification and validation to verify that the offline and online treatment recording supports adding treatment results from a radiotherapy treatment. Purpose: Verify offline import is requested, received and possible to sign with device and radio therapy record selected for import for selected session. Criteria: • Verify treatment course table and beam delivery result table in TC overview gets updated with corresponding data for first session. • Verify the device selected for offline import is the delivered device on the session.	Yes. The successful validation of this feature demonstrates that the device is as safe and effective as the predicate device
Treatment delivery integration framework to support communication between RayCare OIS and treatment devices such as Varian TrueBeam	Methodology: System level verification and validation to verify that Treatment delivery interoperability for the treatment devices such as Varian TrueBeam is supported using the treatment delivery integration framework. Purpose: Verify the treatment flow for treatment delivery. Criteria: • The fraction is fully delivered, and the status of the fraction, session and beams is set to Delivered. Compare the delivered meterset, the couch positions and angles. They should be the same. • The online couch corrections are calculated as the difference between the planned and the delivered couch positions.	Yes. The successful validation of this feature demonstrates that the device is as safe and effective as the predicate device.

From the successful verification and validation activities, the conclusion can be drawn that RayCare 2024A SP1 has met specifications and is as safe, as effective and performs as well as or better than the legally marketed predicate device.

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 differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The Technological Comparison and the Non-Clinical Tests Summary support the safety of the device as compared to the predicate. The software verification and validation and the performance testing demonstrate that the subject device performs as well as the predicate device.

Therefore, the RayCare 2024A SP1 is substantially equivalent to the RayCare 3B cleared under K200487.