



RaySearch Laboratories AB (publ)
% David Hedfors
Quality and Regulatory Affairs Director
Eugeniavägen 18
Stockholm, 113 68
Sweden

April 15, 2022

Re: K220141
Trade/Device Name: RayStation 11B
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: January 10, 2022
Received: January 18, 2022

Dear David 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. 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,

Julie Sullivan, Ph.D.
Assistant Director
Nuclear Medicine and Radiation Therapy
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

Indications for Use

510(k) Number (if known)
K220141

Device Name
RayStation 11B

Indications for Use (Describe)

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.

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

RayStation 11B

Document ID and Title	Version:
510(k) Summary RayStation 11B	1.0

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1. 510(k) Summary

1.1 510(k) owner

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1.2 Contact person

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1.3 Preparation date

January 10th, 2022

1.4 Trade name

The trade name is RayStation.

The marketing name is RayStation 11B and RayPlan 11B.

1.5 Common name

Radiation therapy treatment planning system

1.6 Classification name

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

1.7 Predicate devices

K211867 RayStation 11.0

1.8 Device description

RayStation is a treatment planning system for planning, analysis and administration of radiation therapy and medical oncology treatment plans. It has a modern user interface and is equipped with fast and accurate dose and optimization engines.

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 11B, contains modified features compared to RayStation 11.0 as indicated below:

A simplified license configuration of RayStation is marketed as RayPlan. RayPlan has a limited set of purchasable licenses and some modules will not be accessible. RayPlan is marketed as RayPlan 11B.

EQD2 dose computation (new) - From photon and/or brachy fraction doses, it is possible to compute, deform and accumulate the two Gray equivalent (EQD2) dose. The computation of the EQD2 dose uses the biological linear quadratic model, which is also the basis for the already released biological optimization and evaluation functionality.

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Generation of synthetic CT from CBCT (new) - Two new methods (algorithms) for synthetic CT generation will be included. The synthetic CT images are created by combining information in the CBCT image and a CT image for the specific patient to allow for dose computation using the HU values in the image, as for regular CT images. In RayStation 11.0 it is possible to compute dose on CBCT images for photons using bulk density assignments. The added functionality will improve the photon dose calculation accuracy on CBCT images. Handling of LET and other RBE components (new) - This functionality enables possibility to compute and evaluate the dose weighted LET (Linear Energy Transfer) for proton and light ion plans. LET is an additional dosimetric measure that can be used to assess the radiobiological effect of the proton and light ion radiation. Radiobiological equivalent (RBE) dose is a derived quantity with dependence on both the physical dose and the LET. In RayStation 11.0, it is possible to compute and evaluate RBE doses.

1.9 Intended 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.

1.10 Technological characteristics summary

The technological characteristics are the same for RayStation 11B as for the predicate device RayStation 11.0. 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, by the same development teams, meeting the same requirements for safety and effectiveness.

The device to be marketed, RayStation 11B contains new features as indicated below:

- EQD2 dose computation (new)
- Generation of synthetic CT from CBCT (new)
- Handling of LET and other RBE components (new)

Related to machine learning, there is no change compared to the predicate device.

1.11 Assessment of non-clinical performance data

The test specification of RayStation 11B is a further developed version of the test specification of RayStation 11.0. This is supported by the requirements specification, for which the same is true. The successful verification and validation of RayStation 11B therefore support the substantial equivalence of the above RayStation versions.

EQD2 dose computation (new) – Validation for photon and/or brachy fraction doses were validated as part of the Clinical Evaluation for Brachy and User Site Validation. The validation demonstrates that the dose computation adequate for clinical use.

Generation of synthetic CT from CBCT (new) – Validation of improved photon dose calculation accuracy on CBCT images was performed in CBCT Conversion validation. The validation demonstrates that the dose computation adequate for clinical use.

Handling of LET and other RBE components (new) – Validation of dose weighted LET (Linear Energy Transfer) for proton and light ion plans were performed as part of the Proton PBS Monte Carlo validation. The validation demonstrates that the dose computation adequate for clinical use.

1.12 Test conclusion

The determination of substantial equivalence is not based on an assessment of non-clinical performance data. However, the entire system verification and validation specifications and reports are included in the submission as required by a software device of major concern.

A number of different types of verification activities have been performed:

- System Tests of RayStation

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- Risk analysis-based tests for use error mitigation verification
- Unit and subsystem testing for low-level testing
- Dose engine validation including internal testing
- User validation in cooperation with cancer clinics
- Reviews of design, code and Master Labeling

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

From the successful verification and validation activities, the conclusion can be drawn that RayStation 11B has met specifications and is as safe, as effective and performs as well as or better than the legally marketed predicate device.