RaySearch Laboratories AB (publ)
% Mr. David Hedfors
Quality and Regulatory Affairs Director
Sveavägen 44
Stockholm, 111 34
SWEDEN

September 8, 2021

Re: K211867
Trade/Device Name: RayStation 11.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: June 9, 2021
Received: June 16, 2021

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. 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,

Michael D. O'Hara 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211867

Device Name
RayStation 11.0

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K211867
RSL-D-RS-11.0 510(k) Summary

RayStation 11.0

Table of Contents

1. 510(k) Summary

1.1 510(k) owner

RaySearch Laboratories AB (publ)
Sveavägen 44
111 34 Stockholm
Sweden

Tel: +46 8 510 530 00

1.2 Contact person

David Hedfors
Quality and Regulatory Affairs Director
RaySearch Laboratories AB (publ)
Email: quality@raysearchlabs.com
Tel: +46 722 366 110

1.3 Preparation date

June 9th, 2021

1.4 Trade name

The trade name is RayStation.

The trade name and version number are written together, i.e. “RayStation 11.0” to easily distinguish the submitted device from the primary predicate device RayStation 10.1.

The marketing name is RayStation 11A.

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

K210645 RayStation 10.1

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 11.0, marketing name “RayStation 11A”, contains modified features compared to version 10.1. The main change is planning for the CyberKnife linear accelerator treatment unit.

The device to be marketed supports planning and dose calculation for M6/S7 CyberKnife treatment machines. Older CyberKnife versions are not supported. The CyberKnife has one delivery technique, and different node sets. The node set defines the possible robot positions for different collimations (cones or MLC) and patient geometry (head or body). All node sets available for patient treatments are included in the validation.

CyberKnife specific photon dose engine validation for RayStation 11.0 was performed for the collapsed cone and photon Monte Carlo dose engines. The validation shows that the dose computation is suited for clinical use.

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 11.0 as for the predicate device RayStation 10.1. 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 11.0, marketing name “RayStation 11A”, contains modified features compared to version 10.1. The one main change between the versions is the extension of the treatment planning, to include the CyberKnife linear accelerator treatment unit.

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 11.0 is a further developed version of the test specification of RayStation 10.1. This is supported by the requirements specification, for which the same is true. The successful verification and validation of RayStation 11.0 therefore support the substantial equivalence of the above RayStation versions.

1.11.1 CyberKnife treatment planning dose engine validation

CyberKnife specific photon dose engine validation for RayStation 11.0 was performed for the collapsed cone and photon Monte Carlo dose engines. The validation shows that the dose computation is adequate for clinical use.

RayStation supports planning and dose calculation for M6/S7 CyberKnife treatment machines. Older CyberKnife versions are not supported, which is also stated in the Instructions for Use. The CyberKnife has one delivery technique and different node sets. The node set defines the possible robot positions for different collimations (cones or MLC) and patient geometry (head or body). All node sets available for patient treatments are included in the validation.

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
- 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 11.0 have met specifications and is as safe, as effective and performs as well as or better than the legally marketed predicate device.