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

June 29, 2021

Re: K210645
Trade/Device Name: RayStation 10.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: May 25, 2021
Received: May 28, 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,

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)*
K210645

Device Name
RayStation 10.1

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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1. 510(k) Summary

1.1 510(k) owner

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1.2 Contact person

David Hedfors
Quality and Regulatory Affairs Director
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Tel: +46 722 366 110

1.3 Preparation date

February 26th, 2021

1.4 Trade name

The trade name is RayStation.

The trade name and version number are written together, i.e. “RayStation 10.1” to easily distinguish the submitted device from the primary predicate device RayStation 9.1.

The marketing name is RayStation 10B.

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

1.7.1 Primary predicate device

K200569 RayStation 9.1

1.7.2 Secondary predicate devices

K203172 MOSAIQ Oncology Information System
K181145 Eclipse Treatment Planning System

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 RayCommand application is used for treatment session management including treatment preparation and sending instructions to the treatment delivery devices.

The device to be marketed, RayStation version 10.1, marketing name “RayStation 10B”, contains modified features compared to version 9.1. The main changes are:

- the addition of medical oncology and corresponding update of the intended use. This feature is included in the intended use of the MOSAIQ OIS secondary predicate device.
- the addition of brachy planning. This feature is included in the intended use of the Eclipse TPS secondary predicate device.
    - RayStation 10.1 is compatible with the Bebig SagiNova system afterloader.
- the addition of eye treatment planning (ocular planning) with protons. This feature is included in the intended use of the Eclipse TPS secondary predicate device.
- the extension of the robust planning to take organ motion into account and
- the extension of the treatment session management, from the RayTreat module in RayStation 9.1 to a new module called RayCommand. Like RayTreat, RayCommand is not intended for real-time interaction with the delivery device and does not contain any emergency shutdown functionality.

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 10.1 as for the primary predicate device RayStation 9.1. 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.

Comparing RayStation 10.1 with RayStation 9.1, the newer version includes usability improvements as well as new features.

The most significant new feature is the addition of medical oncology and the corresponding update of the intended use. For this feature the K203172 MOSAIQ OIS is used as a secondary predicate device. Its 510(k) Summary describes this feature as “Generate and keep medication formulary lists and calculate applicable medication dosages for medical oncology”, and this is the same as in RayStation 10.1.

Other main changes are the additions of brachytherapy planning and eye planning, aka ocular planning. For these features the K181145 Eclipse Treatment Planning System is used as a secondary predicate device. Its 510(k) Summary describes this feature as “Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.” This is the same features as in RayStation 10.1.

Other significant changes are:

- the extension of the robust planning to take organ motion into account and
- the extension of the treatment session management, from the RayTreat module in RayStation 9.1 to a new module called RayCommand. Like RayTreat, RayCommand is not intended for real-time interaction with the delivery device and does not contain any emergency shutdown functionality.

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

1.11 Assessment of non-clinical performance data

The test specification of RayStation 10.1 is a further developed version of the test specification of RayStation 9.1. This is supported by the requirements specification, for which the same is true. The successful verification and validation of RayStation 10.1 therefore support the substantial equivalence of the above RayStation versions.

1.11.1 Brachytherapy TG43 dose calculation performance data

RayStation 10.1 accurately models the output from single sources and from sources combined into brachytherapy treatment setups in clinical plans. Since the TG43 dose computation formalism treats the full patient geometry as water, no dedicated test cases for validation of heterogenous geometries are included in the specification. This also means that all doses are reported as dose-to-water with radiation transport in water, D^{w}_{w}.

The brachy TG43 dose computation algorithm in RayStation10B has been successfully validated for accuracy in clinically relevant settings according to specification.

1.11.2 Medical oncology dose calculation performance data

Medical oncology planning in RayStation supports dose calculation based on patient weight, patient body surface area, and flat-rate dose specification. These units of calculation are used in the majority of medical oncology regimens and are the available options in other systems.

Numerous publications describe features of computerized treatment planning for medical oncology that reduce medication errors and improve workflows. The RayStation medical oncology functions have been validated to be appropriate, when used by an intended qualified user according to the Instructions for Use, for supporting medical oncology planning workflows.

1.11.3 Proton ocular treatment dose calculation performance data

The validation covers ocular treatments using the single scattering (SS) delivery technique. Since ocular treatments require small field sizes, achieved by using a field-specific block aperture, the generated Spread Out Bragg Peaks (SOBPs) are approximately laterally uniform. Hence, the SS delivery technique is modelled in RayStation as the double scattering (DS) treatment technique. A range compensator is not used.

The proton dose computation for proton ocular treatments in RayStation 10.1 has been successfully validated for accuracy in clinically relevant settings according to specification.

1.11.4 Robust planning of organ motion performance data

The robustness of a plan can be evaluated by taking uncertainties such as CT inaccuracy and setup errors into account. Robustness handling in RayStation 10.1 has been expanded to also take the uncertainty of the patient's internal organ motion into account. Based on user defined criteria the system computes a set of scenario doses for evaluation.

Deformed image sets can be generated to simulate organ motion without taking multiple CT/CBCT/MR scans of the patient. Structures that are not considered to move can also be used as input to the deformation by being specified as fixed. When the new anatomy has been defined, all other structures will be mapped deformably to the generated deformed image sets.

The generated motion image sets may be used both for evaluation and as input when planning robustly against intra-fractional or inter-fractional organ motion.

The robust planning of organ motion in RayStation 10.1 has been successfully validated according to specification.

1.12 Test conclusion

The determination of substantial equivalence compared to the primary predicate device 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, including the brachytherapy TG43, the medical oncology and the proton ocular treatment dose calculations and the robust planning of organ motion performance data, the conclusion can be drawn that RayStation 10.1 have met specifications and is as safe, as effective and performs as well as or better than the legally marketed primary predicate device.