RaySearch Laboratories AB (publ)
% Ms. Viktoria Hammarstedt
Quality and Regulatory Affairs Specialist
Sveavägen 44
Stockholm, 11134
SWEDEN

June 10, 2020

Re: K200487
Trade/Device Name: RayCare 3.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: May 11, 2020
Received: May 13, 2020

Dear Ms. Hammarstedt:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200487

Device Name
RayCare 3.1

Indications for Use *(Describe)*
RayCare is an oncology information system used to support workflows and scheduling, as well as clinical information, planning and treatment management for oncology care. RayCare may be used in the transfer, storage, conversion and display of patient data in all areas of cancer care including radiation therapy, medical oncology and surgical oncology.
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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5. 510(k) Summary

K200487

5.1 510(k) owner

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5.2 Contact person

Viktoria Hammarstedt
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5.3 Preparation date

February 19, 2020

5.4 Trade name

The trade name is RayCare.
The trade name and version number are written together, i.e. “RayCare 3.1”.
The marketing name is RayCare 3B.

5.5 Common name

Radiation therapy treatment planning system

5.6 Classification name

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

5.7 Predicate device

K191384, RayCare 2.3 Oncology Information System

Product code: MUJ, Regulation number: 892.5050

5.8 Device description

RayCare is an oncology information system that supports healthcare professionals in managing cancer care. The system is structured in functionality modules that are listed below.
RayCare is a software-only system 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.

- Patient clinical data
- Care administration
- Clinical notes and documents
- Workflow and task management
- Charge capture
- Scheduling and calendar functions
- PACS
- Image viewer
- Simulation and imaging
- System administration
- Authentication, authorization and audit logging

- Hospital system integrations

5.9 Technological characteristics summary

The technological characteristics are the same for RayCare 3.1 as for the predicate device.

Comparing RayCare 3.1 with RayCare 2.3, 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.

Both devices include management of electronic patient charts, image reviewing and archiving, comparisons of treatment plans and dose coverage and treatment setup review and recording.

5.10 Assessment of non-clinical performance data

The verification and validation of RayCare 3.1 is based on the intended use and functionalities included in a standard oncology information system, and on the standards ISO 14971, IEC 61217, IEC 62304 and IEC 62366. The successful verification and validation of RayCare 3.1 therefore support the substantial equivalence to the RayCare 2.3 Oncology Information System predicate device.

5.11 Test conclusion

The summary of the performed non-clinical tests shows RayCare 3.1 is as safe and effective and performs as well as the predicate device.