GMV Soluciones Globales Internet S.A.U.
℅ Lorry Weaver
Regulatory Consultant
Qserve Group US, Inc.
350 S. Main Street, Suite 309
DOYLESTOWN, PA 18901

May 17, 2024

Re: K233236
Trade/Device Name: Radiance V5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: September 28, 2023
Received: September 28, 2023

Dear Lorry Weaver:

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.

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K233236

Device Name
Radiance V5

Indications for Use *(Describe)*
Radiance V5 is a software system intended for treatment planning and analysis of radiation therapy administered with devices suitable for intraoperative radiotherapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

The intended users of Radiance V5 shall be clinically qualified radiation therapy staff trained in using the system.

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.***

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# 510(k) Summary

## 1. SUBMITTER

Submitter Name: GMV Soluciones Globales Internet S.A.U.
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Contact Person: Carlos Illana Alejandro

Date Prepared: 28 September 2023

## 2. DEVICE

Device Trade Name: Radiance V5

Common Name: Radiation Treatment Planning Software

Regulation Name: Medical charged-particle radiation therapy system
Regulation Number: 21 CFR 892.5050
Product Code: MUJ
Device System, Planning, Radiation Therapy Treatment

## 3. PREDICATE DEVICE

Predicate Devices: K171885 Radiance V4

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

## 4. DEVICE DESCRIPTION

Radiance V5 is a treatment simulation tool with faster Monte-Carlo simulation, multi-modal planning based on modern imaging standard for intraoperative

radiotherapy (IORT). A software program for planning and analysis of radiation therapy plans. Typically, a treatment plan is created by importing patient images obtained from a CT scanner, defining regions of interest , deciding on a treatment setup and objectives, optimizing the treatment parameters, comparing alternative plans to find the best compromise, computing the clinical dose distribution, approving the plan and exporting it.

## 5. INDICATIONS FOR USE

Radiance V5 is a software system intended for treatment planning and analysis of radiation therapy administered with devices suitable for intraoperative radiotherapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

The intended users of Radiance V5 shall be clinically qualified radiation therapy staff trained in using the system.

## 6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

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|---|---|
| Summary of Technological Characteristics | The technological characteristics are essentially the same as those of the predicate.<br>Both devices produce treatment plans with corresponding dose distributions computed using a three dimensional dosimetry engine. Both devices have a function of electronic approval of treatment plans by trained and authorized staff, and export in DICOM format for commencing treatment or archiving. |
| Substantial Equivalence | From the standpoint of both functionality and workflow the Radiance V5 device is substantially equivalent to the identified predicate as follows:<br>• Within Radiance V5 and its predicate Radiance V4, the user can adjust parameters to achieve a predicted outcome, rather than make a decision intra-operatively.<br>• Radiance V5 and its predicate Radiance V4 are designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with malignancies.<br>• Radiance V5 and its predicate Radiance V4 provide treatment plans with estimates of dose distributions expected during the proposed treatment, and may be |

used to administer treatments after review and approval by qualified medical personnel.
- Radiance V5 and its predicate Radiance V4 use externally acquired medical images and user input to achieve the result.

Radiance V5 introduces a redesigned treatment planning user interface workflow and multi-modal multi-image planning. DICOM functionalities have been improved, and Hybrid Monte Carlo dose computations are now GPU-based for improved speed. These changes allow for improved usability of the software and improved simulation; however the dose distribution computation algorithms are identical to those implemented in Radiance V4 except dose painting and pencil beam calculations have been removed. These calculations were less accurate than Hybrid Monte Carlo but were able to be calculated faster. In Radiance V5 the speed of the Hybrid Monte Carlo calculations made these less precise calculations unnecessary.

## 7. PERFORMANCE DATA

Non Clinical Data

Validation and Verification Testing carried out on Radiance V5 indicates that it meets its predefined products requirements and requirements from the following product standards:

- IEC 61217 Radiotherapy equipment - Coordinates, movements and scales
- IEC 62083 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
- IEC 62304:2006 Medical device software – Software life cycle processes
- IEC 62366 Medical devices - Application of usability engineering to medical devices

Clinical Data

The predecessor of Radiance V5 system, i.e., Radiance – K112060, has been tested clinically. This Clinical Study evaluated the effectiveness and repeatability of the planning process in IORT (Intra-Operative Radio Therapy) with Radiance in regard to the current modalities and the current uncertainties in regard to (manual) treatment planning. The changes in Radiance V5 do not modify basic functionality/workflow in which that study was performed.

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| | Therefore, the Clinical Study conducted for Radiance and data collected can be safely extrapolated and is also valid for Radiance V5, moreover all new design features have been successfully validated in non-clinical tests. |
| Software Verification and Validation Testing | Radiance V5 was designed and developed in accordance with IEC 62304 and as recommended by FDA's Guidance, "Content of Premarket Submissions for Device Software Functions". Radiance V5 was considered to fall into the Enhanced Documentation category. |

## 8. CONCLUSION

The information discussed above demonstrates that the Radiance V5 device is substantially equivalent to the predicate device.