DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 25, 2017

GMV Soluciones Globales Internet S.A.U.
% Patsy Trisler Jd, Rac
Consultant
Qserve Group US Inc.
5600 Wisconsin Avenue
Chevy Chase, Maryland 20815

Re: K171885
Trade/Device Name: Radiance V4
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: June 23, 2017
Received: June 26, 2017

Dear Patsy Trisler Jd, Rac:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171885

Device Name
Radiance V4

Indications for Use *(Describe)*

Radiance V4 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 V4 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.

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."

510(k) SUMMARY – Radiance V4

I. SUBMITTER	
Submitter Name:	GMV Soluciones Globales Internet S.A.U.
Submitter Address:	Isaac Newton,11. 28760, Tres Cantos. Madrid, Spain
Contact Person: **Telephone #:**	Carlos Illana +34 918072100
Date Prepared:	23 June 2017
II. DEVICE	
Device Trade Name:	Radiance V4
Common and Classification Name(s):	Medical charged-particle radiation therapy system
Classification #:	21 CFR 892.5050
Product Code	MUJ
Regulatory Class	2
Review Panel	Radiology
III. PREDICATE DEVICE	K153368, Radiance V3
IV. DEVICE DESCRIPTION	Radiance V4 is a planning tool for intraoperative radiotherapy (IORT), an application that provides a simulation of the dose distribution according to the parameters involved in the procedure. These parameters in IORT include the geometry of the applicator, its orientation and position with respect to the patient and IORT device parameters. Radiance V4 is designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer. The user can adjust parameters to achieve a predicted outcome, rather than make a decision intra-operatively. The created treatment plans provide estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by qualified medical personnel.
DESCRIPTION OF DEVICE MODIFICATIONS	The change(s) to the predicate Radiance V3 are as follows: 1. Dose calculated in a volume orientated to the applicator axis to improve accuracy of the dose in the first millimeters to the applicator surface. 2. Calculation of water equivalent dose to be able to introduce treatment parameters in the dose delivery device software.

	3. User data import/export functionality to exchange data between radiance stations and to allow backups. 4. Reconfiguration of the patients' database to give more information to the user. 5. Improve the usability of the user interface and make it available to be used in a touchscreen. 6. Synchronization with the device calibration directory to avoid inconsistencies. 7. Check of computer resources (memory and hard drive availability). 8. Include the capability to introduce several calibration tables for different CT scans.

V. INDICATIONS FOR USE	Radiance V4 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 V4 shall be clinically qualified radiation therapy staff trained in using the system.
VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES	The Radiance V4 has the same intended use as the predicate. There are no fundamental technological differences between the predicate and the modified device. The only modification(s) are as noted. To address these differences, performance testing was provided.
VI. SUMMARY OF PERFORMANCE DATA AND DESIGN CONTROLS	A Risk Analysis was performed according to ISO 14971:2007 and documentation was included in the 510(k) to assess the modifications and the impact on performance and safety. The changes are included in requirement document and the design document is updated accordingly. Finally, the test cases are included or changed in test document to test the modifications. As a result, design verification testing was performed to assure the use of

	the changes was appropriate, safe and effective for the intended use.
VIII. CONCLUSION OF SUBSTANTIAL EQUIVALENCE	The information and data provided in this Special 510(k) establish that the modified device is substantially equivalent in the intended use, design, principle of operation, technology, materials, specifications and performance to the predicate.