



Food and Drug Administration
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GMV Soluciones Globales Internet S.A.U.
% Ms. Patsy Trisler
Regulatory Consultant
Qserve Group US Inc.
P.O. Box 940
CHARLESTOWN NH 03603

February 16, 2016

Re: K153368
Trade/Device Name: Radiance V3
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 19, 2015
Received: November 23, 2015

Dear Ms. Trisler:

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 yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a faint, large watermark of the FDA logo.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153368

Device Name

Radiance V3

Indications for Use (Describe)

Radiance V3 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 V3 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.

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510(k) Summary

1. SUBMITTER

Submitter Name: GMV Soluciones Globales Internet S.A.U.
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Date Prepared: 30 October 2015

2. DEVICE

Device Trade Name: Radiance V3
Common Name: Radiation Treatment Planning Software
Classification Name, Medical charged-particle radiation therapy system
Number & 21 CFR 892.5050
Product Code: MUJ

3. PREDICATE DEVICE

Predicate Devices: K133655 Radiance V2 (cleared 01/31/2015)

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

4. DEVICE DESCRIPTION

Radiance V3 is a treatment planning system, that is, 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 either manually or semi-automatically, 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.

Radiance V3 improvements over Radiance V2 (K133655) are:

- A Hybrid Monte Carlo dose computation algorithm for photons for the INTRABEAM.
- A beam modeling tool which models and verifies the treatment unit model with measurements for the INTRABEAM.
- An improved DICOM interface including PACS query&retrieve functionality, Storage SCP and DICOM.RT Structures and Dose exportation.

The list of compatible IOERT/IORT devices are:

- Intrabeam (a Carl Zeiss product)
- NOVAC7 and NOVAC11 (a SIT product)
- LIAC10 and LIAC12 (a SIT product)
- MOBETRON (an IntraOp Medical product)
- Conventional LINACs with adapted cylindrical IOERT applicators (telescopic or fixed ones).

Radiance V3 has been tested with Elekta/Precise and Varian/21EX LINACs with particular IOERT cylindrical telescopic applicators.

Characteristics of radiance include:

1. Image manipulation and visualization
2. IORT applicator simulation
3. Contouring manual and interpolation tools
4. Dose calculation algorithms, including:
 - a. For Intrabeam, Dose Painting for a fast (a few seconds) interpolation of PDD around the applicator or Hybrid Monte Carlo for a good combination of computation time (a few minutes) and accuracy.
 - b. For IOERT, pencil beam for a fast (less than one minute) calculation of the dose or Monte Carlo for a good combination of computation time (between 1-10 minutes in most of the cases) and accuracy.
5. Reporting.
6. DICOM & DICOM.RT compatibility

5. INDICATIONS FOR USE

Radiance V3 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 V3 shall be clinically qualified radiation therapy staff trained in using the system.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Summary of Technological Characteristics	<p>The technological characteristics are essentially the same as those of the predicate.</p> <p>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.</p>
Substantial Equivalence	<p>From the standpoint of both functionality and workflow the Radiance V3 device is substantially equivalent to the identified predicate as follows:</p> <ul style="list-style-type: none">• Within Radiance V3 and its predicate Radiance V2, the user can adjust parameters to achieve a predicted outcome, rather than make a decision intra-operatively.• Radiance V3 and its predicate Radiance V2 are designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with malignancies.

- Radiance V3 and its predicate Radiance V2 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 V3 and its predicate Radiance V2 use externally acquired medical images and user input to achieve the result.

The Radiance V3 dose distribution computation algorithms are identical to those implemented in Radiance V2 except for Hybrid Monte Carlo algorithm for INTRABEAM that has been added. Radiance V2 dose calculation algorithm is what we call 'Dose Painting' which is an interpolation of the PDD around the applicator (assuming isotropy). Hybrid Monte Carlo algorithm corrects the dose according to the tissue density which provides a more accurate simulation of the dose received to the tissue. Verification tests were written and executed to ensure that the system is working as designed. Over 150 tests were executed, including tests to verify requirements for new product functionality, tests to ensure the risks mitigation functions as intended, and regression tests to ensure continued safety and effectiveness of existing functionality. Radiance V3 passed testing and was deemed safe and effective for its intended use.

7. PERFORMANCE DATA

Non Clinical Data	Validation and Verification Testing carried out on the Radiance V3 indicates that it meets its predefined products requirements and requirements from the following product standards: <ul style="list-style-type: none">• IEC 61217 Radiotherapy equipment - Coordinates, movements and scales• IEC 62083 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems• IEC 62366 Medical devices - Application of usability engineering to medical devices
Clinical Data	Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Validation testing involved simulated clinical workflows, and algorithm testing which validated the accuracy of dose calculation functions using a simulated clinical setup. The product was deemed fit for clinical use.

Software Verification
and Validation
Testing

Item 4b of Table I in the FDA Guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices asks, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems..." Radiance V3 does not directly control the linear accelerator that delivers the radiation. Once completed, plans are reviewed and approved by qualified clinicians and may be subject to quality assurance practices before treatment actually takes place. There is no automatic link between the Radiance V3 software and the linear accelerator. However, should a flaw in the treatment plan escape the notice of the qualified professionals using the Radiance V3 system, serious injury or death could result. Therefore, we believe Radiance V3 to be of major level of concern.

8. CONCLUSION

The information discussed above demonstrates that the Radiance V3 device is substantially equivalent to the predicate device.

Summary of Technical Characteristics and Comparison to Predicate

Feature	New Device: Radiance V3	Predicate: Radiance V2
510(k) Number	K153368	K133655
Manufacturer	GMV Soluciones Globales Internet S.A.U.	GMV Soluciones Globales Internet S.A.U.
Classification # & Product Code	21 CFR 892.5050 MUJ	21 CFR 892.5050 MUJ
Indication for use	<p>Radiance V3 is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with devices suitable for intraoperative radiotherapy.</p> <p>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.</p> <p>The system functionality can be configured based on user needs.</p> <p>The intended users of Radiance V3 shall be clinically qualified radiation therapy staff trained in using the system.</p>	<p>Radiance V2 is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with devices suitable for intraoperative radiotherapy.</p> <p>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.</p> <p>The system functionality can be configured based on user needs.</p> <p>The intended users of Radiance V2 shall be clinically qualified radiation therapy staff trained in using the system.</p>
System Design	Software only	Software only
Calculation for electrons	<p>Dose distributions computed using a three dimensional dose engine.</p> <p>Pencil Beam computation and Monte Carlo Computation for electrons</p>	<p>Dose distributions computed using a three dimensional dose engine.</p> <p>Pencil Beam computation and Monte Carlo Computation for electrons</p>
Calculation for photons	Dose Painting (Planning calculation interpolation of PDD measurements) and Hybrid Monte Carlo computation for INTRABEAM.	Dose Painting (Planning calculation interpolation of PDD measurements)

Feature	New Device: Radiance V3	Predicate: Radiance V2
Input	Externally acquired patient medical images and user input. Calibration files and beam modeling measurements for INTRABEAM.	Externally acquired patient medical images and user input. Calibration files for INTRABEAM.
Output	Treatment plans with corresponding dose distributions	Treatment plans with corresponding dose distributions
Plan review and approval	Allows electronic approval of treatment plans by trained and authorized staff	Allows electronic approval of treatment plans by trained and authorized staff
Dose calculation algorithm confirmation	Algorithms confirmed for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings.	Algorithms confirmed for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings.
Beam modeling tool	Beam modeling of the treatment unit based on relative measurements and output factors.	Beam modeling of the treatment unit based on relative measurements and output factors.