Radformation, Inc.
% Mr. Kurt Sysock
Co-founder/CEO
335 Madison Avenue, 16th Floor
NEW YORK NY 10017

December 1, 2017

Re: K171352
Trade/Device Name: EZFluence
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, MUJ
Dated: October 4, 2017
Received: October 11, 2017

Dear Mr. Sysock:

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 (DICE) 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 (DICE) 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 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)*

K171352

Device Name
EZFluence

Indications for Use *(Describe)*
EZFluence is intended to assist radiation treatment planning professionals in generating optimal fluences for producing a homogeneous dose distribution in external beam radiation therapy treatment plans consisting of photon treatment fields.

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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Section 5. 510(k) Summary

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

5.1. Submitter's Information

Table 1 : Submitter's Information	
Submitter's Name:	Kurt Sysock
Company:	Radformation, Inc.
Address:	335 Madison Avenue, 16th Floor New York, NY 10017
Contact Person:	Alan Nelson Chief Science Officer, Radformation
Phone:	518-888-5727
Fax:	---------
Email:	anelson@radformation.com
Date of Summary Preparation	05/01/2017

5.2. Device Information

Table 2 : Device Information	
Trade Name:	EZFluence
Common Name:	Oncology Information System
Classification Name:	Class II
Classification:	Medical charged-particle radiation therapy system, dosimetric quality control system
Regulation Number:	892.5050
Product Code::	IYE
Classification Panel:	Radiology

5.3. Predicate Device Information

Eclipse Treatment Planning System (K152393)

5.4. Device Description

The EZFluence device (model RADEZ) is software is intended to assist radiation treatment planning professionals in generating optimal fluences for producing a homogeneous dose distribution in external beam radiation therapy treatment plans consisting of photon treatment fields. Inputs are obtained from plan and patient data obtained from the Eclipse Treatment Planning System (also referred to as Eclipse TPS) of Varian Medical Systems. EZFluence runs as a dynamic link library (DLL) plugin to Varian Eclipse.

It is designed to run on the Windows Operating System. EZFluence performs calculations on the plan obtained from Eclipse TPS (Version 13.5 (K141283) and Version 13.7 (K152393)) which is a software device used by trained medical professionals to design and simulate radiation therapy treatment plans for malignant or benign diseases.

5.5. Indications for Use

EZFluence is intended to assist radiation treatment planning professionals in generating optimal fluences for producing a homogeneous dose distribution in external beam radiation therapy treatment plans consisting of photon treatment fields.

5.6. Technological Characteristics

EZFluence (Subject Device) makes use of a Predicate Device, Eclipse Treatment Planning System (K152393) for substantial equivalence comparison.

5.6.1. EZFluence vs. Eclipse Treatment Planning System (K152393)

The Eclipse Treatment Planning System (TPS) External Beam Planning workspace has two features that are considered substantially equivalent with the functionality provided by EZFluence:

1. Irregular Surface Compensator
2. Optimal Fluence Editing

Table 3: Substantial Equivalence Table for EZFluence

Parameters	Subject Device: EZFluence Radformation	Predicate Device: Eclipse Treatment Planning System, Varian Medical Systems (K152393)	Equivalence
Indications for use	Used to assist radiation treatment planners in generating optimal fluences for external beam radiation therapy treatment plans with photon treatment fields.	Used to plan radiotherapy treatments for patients with malignant or benign diseases.	Subject Device is a subset of the Predicate Device

Pure software	Yes	Yes	Equivalent
Intended users	Trained medical professionals to design and simulate radiation therapy treatments	Trained medical professionals to design and simulate radiation therapy treatments	Equivalent
OTC/Rx	Rx	Rx	Equivalent
EZFluence vs. Eclipse Irregular Surface Compensator			
Functionality	Optimizes optimal fluences for treatment fields to obtain a homogeneous dose in the middle of the patient and to control the maximum dose allowed in the patient.	Optimizes optimal fluences for a specific field to obtain a homogeneous dose at a plane with depth specified by the user.	Minor differences
EZFluence vs. Eclipse Optimal Fluence Editing			
Functionality	Allows user to manually change fluence intensities of an optimal fluence.	Allows user to manually change fluence intensities of an optimal fluence.	Equivalent

As shown in Table 3, EZFluence's indications for use are a subset of Eclipse TPS's indication for use, and the core functionality provided by EZFluence is substantially equivalent with Eclipse TPS's Irregular Surface Compensator and Optimal Fluence Editing features.

5.6.2. Differences

The minor differences between EZFluence and the Irregular Surface Compensator are as follows:

1. EZFluence automatically preserves static multi-leaf collimator blocking by assigning 0 fluence intensity wherever the field was blocked while Eclipse Irregular Surface Compensator does not. By doing this, EZFluence increases safety and efficiency as radiation treatment planners generally have to manually set fluence intensities to 0 wherever there were blocks in the original treatment plan (a step that can easily be forgotten, inadvertently increasing dose, in breast radiotherapy for example, to the heart).
2. EZFluence automatically adds "flash" wherever the field does not intersect the body by extending the fluence nearest to the edge of the patient to the edge of the field. High quality breast radiation therapy, for example, always requires flash in order to ensure the breast is adequately dosed with radiation even when there are day-to-day setup errors. The Eclipse Irregular Surface Compensator does not account for flash and so

the user must manually add flash in order to ensure high quality treatment when they use it for breast treatments. In this way, EZFluence's differences from the Irregular Surface Compensator only increase safety relative to the predicate device.

3. Because EZFluence simultaneously generates optimal fluences for multiple beams instead of for single beams as the Eclipse Irregular Surface Compensator does, EZFluence produces optimal fluences that result in a generally more acceptable and high quality homogeneous dose distribution. Thus the differences between EZFluence and Eclipse Irregular Surface Compensator represent an increase in safety and quality by EZFluence.
4. EZFluence allows the user to limit the maximum dose to the patient while the Eclipse Irregular Surface Compensator does not have that feature.

5.7. Performance Data

As with the Predicate Device, no clinical trials were performed for EZFluence. Verification tests were performed to ensure that the software works as intended and pass/fail criteria were used to verify requirements.

5.8 Conclusion

EZFluence is deemed substantially equivalent to the Predicate Device, Eclipse Treatment Planning System (K152393) due to the similarities with the Irregular Surface Compensator and Optimal Fluence Editing features of Eclipse. Verification and Validation testing and Hazard Analysis demonstrate that EZFluence is as safe and effective as the Predicate Device. The minor technological differences between EZFluence and the Predicate Device do not raise any questions on the safety and effectiveness of the Subject Device.