August 31, 2026

Radformation, Inc.
Jennifer Wampler
Senior Regulatory Affairs Specialist
261 Madison Ave.
9th Floor
New York, New York 10016

Re: K261718
Trade/Device Name: EZFluence (RADEZ V2)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: August 3, 2026
Received: August 4, 2026

Dear Jennifer Wampler:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261718

Please provide the device trade name(s).

EZFluence (RADEZ V2)

Please provide your Indications for Use below.

EZFluence (RADEZ V2) 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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510(k) Summary (K261718) - EZFluence (RADEZ V2)

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.

1. Submitter's Information

Table 1: Submitter's Information	
Submitter's Name:	Kevin Robinson
Company:	Radformation, Inc.
Address:	261 Madison Avenue, 9th Floor New York, NY 10016
Contact Person:	Jennifer Wampler Sr.Regulatory Specialist, Radformation
Phone:	844-723-3675
Fax:	---------
Email:	regulatory@radformation.com
Date of Summary Preparation	5/21/2026

2. Device Information

Table 2 : Device Information	
Trade Name:	EZFluence (RADEZ V2)
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, MUJ
Classification Panel:	Radiology

3. Predicate Device and Reference Device Information

Predicate Device

EZFluence (RADEZ V2) (Subject Device) makes use of its prior submission - EZFluence (K171352) - as the primary Predicate Device. The Indications for Use, patient population, functionality and technical components of this Predicate Device remain unchanged in EZFluence (RADEZ V2). This submission is intended to build on the functionality and technological components of the 510(k) cleared EZFluence (also referred to in K171352 as Model RADEZ).

Reference Device

With the additions included in the submission, EZFluence (RADEZ V2) also makes use of Eclipse Treatment Planning System v16.0 (K200608) as a Reference Device for the new modulated treatment planning optimization module. The reference device is utilized to confirm state-of-the-art assumptions and is utilized as a test device for workflow validation.

4. Device Description

The EZFluence (RADEZ V2) Device is software that utilizes treatment data, image data, and structure set data obtained from supported Treatment Planning System (TPS) Application Programming Interfaces (APIs) or DICOM files as well as dose goals specified by the user to generate optimal fluence files, viewable as estimated doses, that are tailored to result in an optimally homogeneous dose distribution for external beam radiation therapy with photon treatment fields. Optimization may occur within EZFluence (RADEZ V2) for supported plan types or by leveraging the TPS optimizer. Optimal fluence files utilize the TPS algorithm for final dose calculation.

It is designed to run on supported Windows Operating Systems. EZFluence (RADEZ V2) performs dose estimations on the provided supported treatment data. Supported Treatment Planning Systems are used by trained medical professionals to calculate final radiation therapy doses and final plan approval for the treatment of malignant or benign diseases.

Key changes from the Predicate Device are summarized in the table below:

EZFluence - Version History Table - Post-K171352	
Release Version*	Change Description
1.1	Version 1.1 updates added organ-at-risk selection for fluence generation identification, dual-energy photon beam support, and added the Administration Application for configurable settings to allow user defaults versus needing to manually set them in the UI each launch for workflow usability improvements.
1.2	Version 1.2 introduced PTV_EVAL_EZ structure generation/display (already being generated on the backend), DVH view with renormalization tools, field-in-field generation, and automatic Eclipse V15.1+ plan import via the existing API compatibility.
1.3	Version 1.3 updates added estimated dose display, recommended calculation point generation, RTOG 1005 constraint comparison (display values only), and improved the existing dose estimation for more accurate agreement with Eclipse final calculated doses.
1.4	Version 1.4 introduced multi-site support within the same plan for improved usability, Machine MLC Models configuration, additional machine/MLC compatibility, and parallel processing for improved optimization speed.

EZFluence - Version History Table - Post-K171352	
Release Version*	Change Description
2.0	Version 2.0 updates included an Interface redesign with beam's eye view visualization, additional beam configuration plan optimization, expanded boost and field weight options were opened up to the user to set on the frontend (versus setting default on the backend), and additional Administration Application settings for improved usability.
2.1	Version 2.1 introduced broadened Eclipse API version compatibility (V11, V13.5, V15.0) to improve upon the existing API functions, added user optimization options, BEV UI improvements, and PTV_EVAL_EZ export configuration via the Eclipse API (functionality existed).
2.2	Version 2.2 introduced editable DVH metrics (reporting values for viewing only), enhanced boost optimization options for improved usability, additional Administration Application settings for improved workflow and default settings, and expanded machine/MLC support.
2.3	Version 2.3 introduced additional optimization tools for improved usability, improved the existing dose estimation for more accurate agreement with Eclipse final calculated doses, and added Administration Application customization options for improved workflow usability.
2.4	Version 2.4 added Active Directory authentication, jaw tracking customization, and expanded machine/MLC compatibility with associated fixes.
2.5	Version 2.5 included expansion of data input functionality to include support for RayStation and Monaco Treatment Planning System (TPS) users through integration with their respective APIs.
2.6	Version 2.6 the ability to create fluences for modulated therapy (such as VMAT) versus utilizing static fields only. (OptiPlan)

5. Indications for Use

EZFluence (RADEZ V2) 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.

6. Technological Characteristics

EZFluence (RADEZ V2) vs. EZFluence (K171352)

EZFluence (RADEZ V2) builds on the FDA clearance provided with EZFluence (K171352). Both the Subject and Predicate Devices are 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.

The Subject Device adds incremental functionality to what exists in the Predicate Device, as noted in the section 4 change history table. The Indications for Use, patient population, functionality, and technical components of the Predicate Device remain unchanged in EZFluence (RADEZ V2). The main UI outputs are equivalent to the Predicate Device as well, allowing the user to properly visualize and analyze planning results, but adding new capabilities expanding the optimization functionality to modulated treatments in order to ensure a customizable output by the user. There were also minor changes related to allowing the user to customize the optimization criteria on a finer level while using the same underlying mechanics. This submission is intended to build on the functionality of the 510(k) cleared EZFluence.

The main technological characteristics of the Subject Device and the Predicate Device remain the same. Both are computer-based software Devices designed to run on supported Windows Operating Systems. Both use treatment data, image data, and structure set data obtained from supported Treatment Planning System Application Programming Interfaces to present field fluences for radiotherapy treatment plans. Both Devices share major functionality such as fluence optimization and dose homogeneity optimization. Both are used by trained medical professionals to assist in the treatment planning process. Both utilize the TPS for final dose calculation.

Table 4: Substantial Equivalence EZFluence (RADEZ V2) vs. Predicate Device		
Parameters	**Subject Device: EZFluence (RADEZ V2)**	**Predicate Device: EZFluence**
EZFluence (RADEZ V2) vs. Predicate Device: **Technological Characteristics**		
Summarized 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. *(Equivalent to Predicate)*	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.
Energy Used and/or Delivered	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients. *(Equivalent to Predicate)*	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients.
Intended users	Trained clinically qualified radiation oncology personnel *(Equivalent to Predicate)*	Trained clinically qualified radiation oncology personnel
OTC/Rx	Rx *(Equivalent to Predicate)*	Rx
Design: Graphical User Interface	Contains a Data Visualization / Graphical User Interface *(Equivalent to Predicate)*	Contains a Data Visualization / Graphical User Interface
Design: Supported Files	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters); DICOM plan, dose, image, structures set files; user-specified treatment planning constraint objectives for use with planning optimization *(Substantially equivalent to Predicate)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters).
Pure software	Yes *(Equivalent to Predicate)*	Yes

Table 4: Substantial Equivalence EZFluence (RADEZ V2) vs. Predicate Device		
Parameters	**Subject Device: EZFluence (RADEZ V2)**	**Predicate Device: EZFluence**
Operating System	Windows Operating System *(Equivalent to Predicate)*	Windows Operating System
EZFluence (RADEZ V2) vs. Predicate Device **Functionality Comparison**		
Input	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters); DICOM plan, dose, image, structures set files; user-specified treatment planning constraint objectives for use with planning optimization *(Substantially equivalent to Predicate)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters).
Functionality	Fluence-based dose estimation for treatment planning use *(Substantially equivalent to Predicate)*	Fluence-based dose estimation for treatment planning use
Output	Calculates and displays estimated doses using the user-set optimization options and incoming plan parameters for user selection and export back to the supported TPS. *(Substantially equivalent to Predicate)*	Calculates and displays estimated doses using the user-set optimization options and incoming plan parameters for user selection and export back to the Eclipse TPS.
EZFluence (RADEZ V2) vs. Predicate Device **Irregular Surface Compensator**		
Input	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters); DICOM plan, dose, image, structures set files. *(Substantially equivalent to Predicate)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters).
Functionality	Optimizes fluences for treatment fields to obtain a homogeneous dose in the middle of the patient or per user-selected structure(s) and control the maximum dose allowed in the patient structures. *(Substantially equivalent to Predicate)*	Optimizes 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 structures.
Output	Generated optimal fluences for final dose calculation within the support TPS. *(Substantially equivalent to Predicate Device)*	Generated optimal fluences for final dose calculation within the support TPS.
EZFluence (RADEZ V2) vs. Predicate Device **Optimal Fluence Editing**		
Input	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters) and DICOM plan, dose, image, structures set files. *(Substantially equivalent to Predicate Device)*	Allows user to manually change Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters).

Table 4: Substantial Equivalence EZFluence (RADEZ V2) vs. Predicate Device		
Parameters	**Subject Device: EZFluence (RADEZ V2)**	**Predicate Device: EZFluence**
Functionality	Allows the user to change the intensities of a fluence. *(Substantially equivalent to Predicate Device)*	Allows the user to change the intensities of a fluence.
Output	Updated dose estimation display and edited fluence files, which may be exported for final dose calculation within the support TPS. *(Substantially equivalent to Predicate Device)*	Updated dose estimation display and edited fluence files, which may be exported for final dose calculation within the support TPS.
EZFluence (RADEZ V2) vs. Predicate Device **Constraint-based Optimization***		
Input	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters); DICOM plan, dose, image, structures set files; user-specified treatment planning constraint objectives for use with planning optimization. *(Substantially equivalent to Predicate Device)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters)
Functionality	Utilizes constraint-based objectives to optimize the treatment plan dose based on the planning data. User may manually change OAR priorities to adjust fluence intensities as well as optionally configure fields within the module. *(Substantially equivalent to Predicate Device)*	Fluence-based dose estimation for treatment planning use from user-provided fields.
Output	Treatment plan with dose from the TPS optimized to the provided constraints with the status *'Unapproved.'* *(Substantially equivalent to Predicate Device)*	Calculates and displays estimated doses using the user-set optimization options and incoming plan parameters for user selection and export back to the Eclipse TPS.

* Subject Device is adding new functionality and UI options as well as directly incorporating constraints for optimization. While these are new features, they function with the same base backend and overall optimization principles of the Predicate Device.

7. Performance Data

As with the Predicate, no clinical trials were performed for EZFluence (RADEZ V2). Verification tests were performed to ensure that the software works as intended, and pass/fail criteria were used to verify requirements. Simulated clinical testing was performed, along with a structured usability analysis to confirm safe and effective usage in a clinical setting as compared to the predicate. Validation testing was performed to ensure that the software was behaving as intended, and results from EZFluence (RADEZ V2) were validated against accepted outputs for known planning parameters from clinically utilized treatment planning systems, including a state-of-the-art reference device.

Validation of the EZFluence OptiPlan module's optimization and TPS dose display functionality for modulated treatment fields (including VMAT) was performed. Testing demonstrated that EZFluence consistently preserved treatment planning data during import from Eclipse to EZFluence, optimization results displayed within EZFluence, and export of data back to Eclipse. Geometry and beam parameters, structures, planning data, dose constraint values, and displayed dose information

remained consistent between Eclipse and EZFluence throughout the evaluated workflows. Dose displays, DVH data, isodose distributions, and constraint evaluation results matched as expected and no unexpected modifications to plan or structure data were observed.

The EZFluence OptiPlan module priority weighting performed as expected, with higher priorities exerting greater influence on the corresponding constraints than lower priorities. Standard clinical workflows also performed as expected across the available EZFluence operational pathways: an initial optimization followed by dose adjustment and “Overwrite Dose” produced a single result plan; re-opening the plan in the OptiPlan module confirmed that dose was preserved and constraints were evaluated correctly. Adjusting a constraint slider and selecting “Resume” with “Copy Plan” created a new plan as expected. All operational functionality executed as expected.

Testing by representative clinical users across representative treatment sites and workflows confirmed that EZFluence, including the OptiPlan module, met applicable clinical planning objectives and performed consistently under the evaluated use conditions. These results provide objective evidence that EZFluence produces clinically acceptable treatment planning results and performs as intended for clinical use on modulated treatment fields, including VMAT.

Performance testing for verification and validation of user-provided constraints and EZFluence OptiPlan optimization versus reference manual SOA workflows was evaluated. DVH-based clinical accuracy was quantitatively measured for optimization and constraint performance relative to protocol objectives and SOA inter-observer variability (IOV). All EZFluence OptiPlan DVH values met their associated clinical NRG protocol goals. Some observations fell outside the observed SOA IOV range; investigation confirmed that none of those differences were clinically meaningful. Meaningful clinical dosimetric accuracy is cited by ICRU 50 as ±5%Rx for target dose, and 2%/2 mm or 3%/3 mm tolerances are frequently applied for radiotherapy plan-delivery quality assurance.

Testing was conducted to validate the new optimization for VMAT is acceptable. The tests conducted focused on target coverage and homogeneity, OAR hot spot evaluation, and OAR sparing. Test sample cases included typical treatment sites such as pelvis, head and neck, lung, and whole-brain hippocampal-sparing plans. Overall, relative to reference manual SOA workflows and published NRG and ICRU objectives, EZFluence OptiPlan DVH outputs for target coverage/homogeneity and OAR dose/volume constraints met protocol goals; quantified deviations outside SOA IOV remained within or below accepted clinical tolerances and were clinically acceptable, thereby verifying and validating user-provided constraint handling and optimization performance.

8. Conclusion

EZFluence (RADEZ V2) is deemed substantially equivalent to the Predicate Device EZFluence (K171352). Verification tests were performed to ensure that the software works as intended, and pass/fail criteria were used to verify requirements. Validation testing was performed to ensure that the software was behaving as intended, and output results from EZFluence (RADEZ V2) were validated against accepted results for known planning parameters from clinically utilized treatment planning systems. All tests passed regression testing. Based on the comparison of intended use, functionality, and performance, the subject device EZFluence (RADEZ V2) is concluded to be substantially equivalent to its predicate device.