Build Correspondence | Convert to PDF

U.S. FOOD & DRUG ADMINISTRATION

April 3, 2026

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

Re: K253962
Trade/Device Name: ClearCheck (RADCC V2.7)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: December 10, 2025
Received: December 11, 2025

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,

SAMUEL T. PELLOM JR -S

Digitally signed by SAMUEL T. PELLOM JR -S
Date: 2026.04.03 11:46:44 -04'00'

for

Lora Weidner
Assistant Director
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.	K253962

Please provide the device trade name(s).

ClearCheck (RADCC V2.7)

Please provide your Indications for Use below.

ClearCheck is intended to assist radiation therapy professionals in generating and assessing the quality of radiotherapy treatment plans. ClearCheck is also intended to assist radiation treatment planners in predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures.

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)

RAD formation

510(k) Summary (K253962) - ClearCheck (RADCC V2.7)

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	12/10/2025

2. Device Information

Table 2 : Device Information	
Trade Name:	ClearCheck (RADCC V2.7)
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

3. Predicate Device and Reference Device Information

Predicate Device
ClearCheck (RADCC V2.7) (Subject Device) makes use of its prior submission - ClearCheck Model RADCC V2 (K220583) - as the primary Predicate Device. The Indications for Use, patient population, functionality, and technical components of this Predicate Device remain unchanged in ClearCheck (RADCC V2.7). This submission is intended to build on the functionality and technological components of the 510(k) cleared ClearCheck RADCC V2.

Reference Devices
With the additions included in the submission, ClearCheck (RADCC V2.7) also makes use of the Eclipse Treatment Planning System v16.0 (K200608) as a Reference Device for the new Chart Rounds module.

ClearCheck (RADCC V2.7) also makes use of AutoContour Model RADAC V4 (K242729) as a Reference Device for the deformed dose viewing functionality.

4. Device Description
The ClearCheck (RADCC V2.7) device is software that utilizes treatment data, image data, and structure set data obtained from supported Treatment Planning System Application Programming Interfaces (APIs) or DICOM files to present radiotherapy treatment plans in a user-friendly manner for user approval of the treatment plan.

It is designed to run on supported Windows Operating Systems. ClearCheck (RADCC V2.7) performs calculations on the incoming supported treatment data. Supported Treatment Planning Systems are used by trained medical professionals to simulate radiation therapy treatments for malignant or benign diseases.

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

ClearCheck - Version History Table - Post-K220583	
Release Version* Release Date	Change Description
2.2	Version 2.2 updates introduced a new Three-View Image Viewer in the Main Window for visualizing 3D dose distributions, with support for BED and EQD2 when applicable. A Chart Rounds module was added to enable reviewing multiple patients within a single application, along with integrated access to ARIA patient documents directly in ClearCheck and Chart Rounds. The release also added the ability to create Deformed Dose Plan Sums using AutoContour-based deformations to map and combine dose across image sets, allowing full evaluation of the resulting distribution. Additionally, usability improvements were made to the Administration application to streamline and simplify template management.
2.3	Version 2.3 introduced the ability to create Plan Sums directly within ClearCheck, building on the Deformed Dose Plan Sums released in Version 2.2. ClearCheck Plan Sums may be generated between plans with a Shared Frame of Reference or through DICOM, Eclipse registrations, or AutoContour registration. This update also enables launching ClearCheck on DICOM files for use outside Varian's Eclipse Treatment Planning System and includes additional Administration settings to further improve usability.

ClearCheck - Version History Table - Post-K220583	
Release Version* Release Date	Change Description
2.4	Version 2.4 updates introduced improvements to the Three-View Image viewer, such as isodose levels and colorwash controls. Usability improvements were also added to Collision Check, Chart Rounds, ClearCheck Standalone, and the Administration Application.
2.5	Version 2.5 introduced several enhancements, including expanded capabilities within the Constraints feature, such as creating Custom Constraints using other calculated constraints and general usability features. Report usability improvements were also added to improve reporting options and customization. Additional usability updates were made to Chart Rounds and ClearCheck Standalone. The release also added three new Plan Checks to improve the assessment of planning.
2.6	Version 2.6 updates included expansion of data input functionality to include support for RayStation and Monaco Treatment Planning System (TPS) users through integration with their respective APIs. Added additional features for BED/EQD2 recovery factors for Plan Sums to allow for more flexibility in calculations.
2.7	Version 2.7 introduces the ability to create Custom Plan Checks, allowing users to run external scripts from ClearCheck and return results for display and reporting. The Collision Check module was updated with an improved collision algorithm, along with UI and usability enhancements. This release also includes an upgraded Three-View Image Viewer offering better usability, functionality, and performance.

5. Indications for Use

ClearCheck (RADCC V2.7) is intended to assist radiation therapy professionals in generating and assessing the quality of radiotherapy treatment plans. ClearCheck (RADCC V2.7) is also intended to assist radiation treatment planners in predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures.

6. Technological Characteristics

ClearCheck (RADCC V2.7) (Subject Device) makes use of its prior submission - ClearCheck RADCC V2 (K220583) - as the Predicate Device. The Indications for Use, patient population, functionality, and technical components of this Predicate Device remain unchanged in ClearCheck (RADCC V2.7). The main UI outputs are equivalent to the Predicate Device as well, allowing the user to properly visualize and analyze the calculations. This submission is intended to build on the functionality and technological components of the 510(k) cleared ClearCheck RADCC V2 (K220583).

The main technological characteristics of the subject device and the primary predicate device remain the same. Both are computer-based software devices designed to run on Windows Operating Systems. Both use treatment data, image data, and structure set data obtained from supported Treatment Planning System Application Programming Interfaces to present radiotherapy treatment plans in a user-friendly way for user approval of the treatment plan. Both devices share major functionality such as Dose Constraints, Plan Checks, Plan Reporting and Plan Comparison. Both are used by trained medical professionals to assist in the treatment planning process. There were minor changes related to refactoring calculations within the Collision Check module.

Table 4: Substantial Equivalence ClearCheck (RADCC V2.7) vs. Predicate		
Parameters	**Subject Device: ClearCheck (RADCC V2.7)**	**Predicate Device: ClearCheck Model RADCC V2 (K220583)**
ClearCheck vs. Predicate and Reference Devices: **Technological Characteristics**		
Summarized Indications for Use	ClearCheck is intended to assist radiation therapy professionals in generating and assessing the quality of radiotherapy treatment plans. ClearCheck is also intended to assist radiation treatment planners in predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures. *(Equivalent to Predicate)*	ClearCheck is intended to assist radiation therapy professionals in generating and assessing the quality of radiotherapy treatment plans. ClearCheck is also intended to assist radiation treatment planners in predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures.
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, structure set, and registration files. *(Substantially equivalent to Predicate)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan data (including treatment field parameters).
Design: Reporting and Data routing	Reporting built-in and user has ability to customize and export the report. *(Equivalent to Predicate)*	Reporting built-in and user has ability to customize and export the report.
Pure software	Yes *(Equivalent to Predicate)*	Yes

Table 4: Substantial Equivalence ClearCheck (RADCC V2.7) vs. Predicate		
Parameters	**Subject Device: ClearCheck (RADCC V2.7)**	**Predicate Device: ClearCheck Model RADCC V2 (K220583)**
Operating System	Windows Operating System *(Equivalent to Predicate)*	Windows Operating System
Input	Treatment data, image data, and structure set data obtained from supported Treatment Planning System and Application Programming interfaces or DICOM plan, dose, image, structure set, and registration files. *(Substantially equivalent to Predicate)*	Treatment data, image data, and structure set data obtained from supported Treatment Planning System and Application Programming interfaces
Dose Constraints	Default set of dose constraints plus additional dose constraints added *(Substantially equivalent to Predicate)*	Default set of dose constraints
Plan Checks	Default set of plan checks plus additional plan checks added *(Substantially equivalent to Predicate)*	Default set of plan checks
Reporting	Improvements to report usability *(Substantially equivalent to Predicate)*	Default reporting functionality
Custom Checks	Allows users to evaluate Plan Checks included in the software and to create Custom Plan Checks. *(Substantially equivalent to Predicate)*	Allows users to evaluate Plan Checks included in the software.
Image Viewer	Enhanced functionality, including registration views *(Substantially equivalent to Predicate)*	Initial Image View functionality
Collision Check	Enhanced collision functionality (i.e. intuitive transit collision handling, ability to verify results) and updated collision detection algorithm *(Substantially equivalent to Predicate)*	Collision detection functionality
Output	Displays planned dose constraints values along with check state indicators. *(Substantially equivalent to Predicate Device)*	Displays planned dose constraints values along with check state indicators.
Functionality	Evaluate dosimetric parameters on Plan Sums created within Eclipse or Plan Sums created within ClearCheck (ClearCheck Plan Sums) that are generated using DICOM/Eclipse Registrations, Shared Frame of Reference, or AutoContour Rigid or Deformable Registrations. *(Substantially equivalent to Predicate)*	Evaluate dosimetric parameters on Plan Sums created within Eclipse.

Table 4: Substantial Equivalence ClearCheck (RADCC V2.7) vs. Predicate		
Parameters	**Subject Device: ClearCheck (RADCC V2.7)**	**Predicate Device: ClearCheck Model RADCC V2 (K220583)**
Output	Displays planned dose constraints values along with check state indicators for single plans, Plan Sums created within Eclipse, and rigid/deformable Plan Sums created within ClearCheck. *(Substantially equivalent to Predicate)*	Displays planned dose constraints values along with check state indicators for single plans and Plan Sums created within Eclipse.

7. Performance Data

As with the Predicate, no clinical trials were performed for ClearCheck (RADCC V2.7). 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 results from ClearCheck (RADCC V2.7) were validated against accepted outputs for known planning parameters from clinically-utilized treatment planning systems. These tests all passed regression testing. Testing details for key features are summarized as follows:

Image Registrations

Included plan sums generated using Shared Frame of Reference registrations, Eclipse registrations, DICOM registrations, AutoContour rigid/deformable registrations, and testing of registrations with different underlying orientations is introduced in version 2.7. Testing was performed by generating reference plans and plan sums using clinically supported treatment planning systems and comparing constraint evaluation results calculated by ClearCheck (RADCC V2.7) against expected values derived from manual calculations or TPS DVH-based calculations. ClearCheck (RADCC V2.7) outputs for all constraint types were compared against these expected values across each registration scenario. Acceptance criteria for constraint validation testing required agreement within 0.5% for non-volume constraint types. For volume-based constraints, acceptance tolerance was increased to 10% due to differences in DVH binning and the small volume sizes evaluated. Version 2.7 additionally verified orientation transformations by confirming that the mean dose of structures in the plan sum matched the summed contribution from component plans, confirming correct registration and spatial transformation handling.

Deformed Dose

Testing verified the correct application of ClearCheck (RADCC V2.7)-accepted deformable registrations provided by AutoContour. A known deformable registration generated by intentionally modifying image pixel spacing to produce a predictable deformation was used to test the deformed dose functionality. Deformed dose distributions generated by ClearCheck (RADCC V2.7) were compared against analytically determined or manually calculated expected results. Additional clinical test cases compared the DVHs and structure dose metrics between the original and

deformed dose distributions. Acceptance criteria required that deformed dose results agree with expected values within a 3% tolerance. All test scenarios passed the defined acceptance criteria. DVH comparisons, mean dose comparisons, and maximum dose comparisons demonstrated agreement within tolerance limits and confirmed that ClearCheck (RADCC V2.7) correctly applies deformable registrations when evaluating dose distributions.

Collision Check

Several enhancements to Collision Check were included in v2.7, such as intuitive transit collision handling, the ability to verify results, and improvements to the collision detection algorithm. Collision Check testing included functionality of all Collision Check options and machine/patient variables (i.e. electron cones, presence of On Board Imagers, presence of bolus, etc.). Collision results were compared to identical scenarios in the predicate device and tested for agreement between the two collision algorithms. Acceptance criteria required an identical collision status between the two algorithms for all test cases.

BED\EQD2

Testing included a comparison between the ClearCheck (RADCC V2.7) calculated results and manual calculations for multiple test cases. Scenarios include BED conservative/non-conservative and EQD2 conservative/non-conservative calculations for single plans, sequentially delivered plan sums with and without recovery factors, and concurrently delivered plan sums with and without recovery factors. Acceptance criteria for BED and EQD2 constraint validation testing required agreement within 0.5% for non-volume constraint types. For volume-based constraints, acceptance tolerance was increased to 10% due to differences in DVH binning and the small volume sizes evaluated.

Contours

Although ClearCheck (RADCC V2.7) does not perform contour generation or allow contour editing in any way, ClearCheck (RADCC V2.7) does support workflows that utilize contours and deformable registrations produced by Radformation's AutoContour product. Contour-display functionality was validated as a part of verifying the correct use of AutoContour-generated deformable registrations for dose deformation and plan sum evaluations. These tests confirm that ClearCheck (RADCC V2.7) accurately displays structure sets and registration information produced externally by AutoContour as it relates to dose and constraint evaluation workflows available in ClearCheck (RADCC V2.7).

8. Conclusion

ClearCheck (RADCC V2.7) has the same intended use and main technological characteristics as the predicate device ClearCheck Model RADCC V2. Verification tests were performed to test functionality and address minor differences between the subject and predicate devices 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 ClearCheck (RADCC V2.7) 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 ClearCheck (RADCC V2.7) is concluded to be substantially equivalent to its predicate device.