December 19, 2025

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

Re: K252863
Trade/Device Name: ClearCalc Model RADCA V2.6
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: November 20, 2025
Received: November 20, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252863

Device Name
ClearCalc Model RADCA V2.6

Indications for Use *(Describe)*
ClearCalc is intended to assist radiation treatment planners in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation algorithm.

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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RAD formation

K252863

510(k) Summary - ClearCalc Model RADCA V2.6

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:	Kurt Sysock
Company:	Radformation, Inc.
Address:	261 Madison Avenue, 9th Floor New York, NY 10016
Contact Person:	Kevin Robinson VP of Regulatory Affairs, Radformation
Phone:	518-888-5727
Fax:	---------
Email:	krobinson@radformation.com
Date of Summary Preparation	9/08/2025

2. Device Information

Table 2: Device Information	
Trade Name:	ClearCalc Model RADCA V2.6
Common Name:	Secondary Check Quality Assurance Software, Patient Quality Assurance Software
Classification Name:	Class II
Classification:	Medical charged-particle radiation therapy system
Regulation Number:	892.5050
Product Code:	MUJ
Classification Panel:	Radiology

3.1. Predicate Device and Reference Device Information

Primary Predicate Device
ClearCalc Model RADCA V2.6 (Subject Device) utilizes its prior submission, ClearCalc Model RADCA V2 (K220582), as the Predicate Device.

Reference Devices
With the additions included in this submission, ClearCalc Model RADCA V2.6 also utilizes SunCHECK (K170307) as a Reference Device for the new electronic portal imaging device (EPID) functionality.

3.2. Primary Predicate Device Change History

ClearCalc Version 2.2 introduced several enhancements designed to improve functionality, usability, and reporting. History tracking has been implemented within the Administration module, accompanied by user interface refinements that enhance overall usability and provide a more intuitive experience. The existing Hand Calculation module included the ability to cache and recall calculations, streamlining workflows and reducing redundant computation. Additionally, support was added to capture data displayed in the user interface for Finite Size Pencil Beam (FSPB) calculations, allowing this information to be seamlessly incorporated into the corresponding calculation report.

ClearCalc Version 2.3 introduced the ability for users to send generated PDF reports directly to their Oncology Information System (OIS), streamlining documentation management and improving integration between calculation outputs and clinical record systems.

ClearCalc Version 2.4 introduced per-structure gamma analysis for both RadMonteCarlo and Finite Size Pencil Beam (FSPB) results, enhancing the existing gamma analysis capabilities by allowing users to define evaluations based on individual structures available within the treatment plan. Additionally, new functionality was added to the electron calculation module, improving the user experience through support for customizable, manually drawn cutouts that provide greater flexibility in electron field modeling.

ClearCalc Version 2.5 included improving the DICOM patient and plan selection usability and providing a more streamlined user experience. RadMonteCarlo functionality was expanded to include features previously available for the Finite Size Pencil Beam (FSPB) algorithm, extending support to log file analysis and CyberKnife machine calculations. Improvements were also made to photon beam data commissioning, simplifying data import and making the commissioning process more efficient and accessible. Additionally, log file functionality was broadened to incorporate an additional C-arm linear accelerator line - Elekta - leveraging existing log file logic to enable detailed analysis of these machine logs. Machine patient-specific QA functionality was enhanced to support the use of pixel intensity maps generated by the machine, similar to the existing log file-based QA approach.

ClearCalc Version 2.6 includes expansion of data input functionality to include support for RayStation and Monaco Treatment Planning System (TPS) users through integration with their respective APIs. Additionally, RadMonteCarlo results are enhanced to provide per-field individual outputs for proton calculations, utilizing the existing computational framework to generate and present this additional level of detail.

4. Device Description

The ClearCalc Model RADCA V2.6 device is software that uses treatment data, image data, and structure set data obtained from a supported Treatment Planning System and Application Programming interfaces to perform a dose and/or monitor unit (MU) calculation on the incoming treatment planning parameters. It is designed to assist radiation treatment planners in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation algorithm.

5. Indications for Use

ClearCalc is intended to assist radiation treatment planners in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation algorithm.

6. Technological Characteristics

Predicate Device
ClearCalc Model RADCA V2.6 (Subject Device) makes use of its prior submission - ClearCalc Model RADCA V2 (K220582) - as the primary Predicate Device. The Indications for Use, patient population, functionality and technical components of this Predicate Device remain unchanged in ClearCalc Model RADCA V2.6. Additionally, the Predicate Device is referenced in its current ability to input, process, and output calculations for machine output files. This submission is intended to build on the functionality and technological components of the 510(k) cleared ClearCalc Model RADCA V2 and is inclusive of the letter to file updates identified as Versions 2.2, 2.3, 2.4 and 2.5.

Similar to the Predicate Device software, ClearCalc Model RADCA V2.6 is designed to run on Windows Operating Systems, performs dose and/or monitor unit (MU) calculations on the incoming supported treatment data, and displays the calculated results to the user. Supported Treatment Planning System and Application Programming Interfaces are used by trained, clinically-qualified radiation oncology personnel to simulate radiation therapy treatments for malignant or benign diseases. The intended user base has not changed from the Predicate Device. ClearCalc may call either its local calculation engine or, optionally, call its Monte Carlo dose calculation engine to perform dose and/or MU calculations (both included in the scope of the Predicate Device). The general function of both of these algorithms remains unchanged, though our effort is to constantly ensure the accuracy of both algorithms. ClearCalc Model RADCA V2.6 also supports processing machine output files, as does the Predicate Device.

Machine output files have multiple formats, such as machine log files and machine pixel intensity maps. These pixel intensity maps are representative of the output of the machine using the treatment planning parameters, just as with machine log output files represent the treatment plan delivery by the machine. ClearCalc Model RADCA V2.6's existing algorithms are utilized for calculation, which are equivalent to the Predicate Device algorithms. The UI outputs are equivalent to the Predicate Device as well, allowing the user to properly visualize and analyze the calculations.

Reference Device

As the new machine output file format is supported with the Subject Device, which is machine output in the form of pixel intensities via the machine's electronic portal imaging device (EPID) output files, an additional Reference Device is sited - SunCHECK (K170307). This is an output format of the machine similar to the currently supported machine log files. With this Reference Device, machine output files in the form of pixel intensities are used for verification of the patient treatment plan, just like machine log files outputs. The Reference Device functionality takes output files from the machine, both machine log files and machine pixel intensities from the EPID device, and calculates the delivered dose using SunCHECK's existing algorithms. This input and calculation is the same for the Subject Device. The calculated dose is then compared to the planned dose, obtained from the treatment plan files for which ClearCalc already supports intake, and displays the analysis and comparison to the user for evaluation, just like machine log file outputs. Instead of using the treatment planning parameters or machine-recorded log files, ClearCalc uses the delivered treatment parameters from the machine pixel files to re-calculate the dose from the given plan. As this functionality has already been researched for accuracy and reliability in the field of radiation oncology, as well as used commercially by several cleared products in-market, this functionality does not raise any new questions in terms of safety and effectiveness.

Due to the technological characteristic similarities to the Predicate Device, the Subject Device raises no new concerns regarding safety and effectiveness.

Table 3: Technological Characteristics
ClearCalc Model RADCA V2.6 vs. Predicate Device and Reference Device

Parameters	Subject Device: ClearCalc Model RADCA V2.6	Predicate Device: ClearCalc Model RADCA V2 (K220582)	Reference Device: SunCHECK (K170307)
Summarized Indications for use	Intended to assist radiation treatment planners in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation algorithm. *(Equivalent to Predicate)*	Intended to assist radiation treatment planners in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation algorithm.	SunCHECK is a software platform intended to collect, detect, compare, calculate, analyze, display, and store radiotherapy quality assurance and dosimetry data.

Table 3: Technological Characteristics ClearCalc Model RADCA V2.6 vs. Predicate Device and Reference Device			
Parameters	**Subject Device: ClearCalc Model RADCA V2.6**	**Predicate Device: ClearCalc Model RADCA V2 (K220582)**	**Reference Device: SunCHECK (K170307)**
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.	None – software only application. The software application does not deliver or depend on energy delivered to or from patients
Intended users	Trained radiation oncology personnel *(Equivalent to Predicate)*	Trained radiation oncology personnel	Trained radiation oncology personnel
OTC/Rx	Rx *(Equivalent to Predicate)*	Rx	Rx
Design: Graphical User Interface	Contains a Data Visualization / Graphical User Interface *(Equivalent to Predicate)*	Contains a Data Visualization / Graphical User Interface	Contains a Data Visualization / Graphical User Interface
Design: Supported files	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data as well as machine treatment log files and electronic portal imaging device files *(Equivalent to Predicate)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data as well as machine treatment log files	Files containing Structure Set, and Treatment Plan (including treatment field parameters) data
Design: Reporting	Reporting built-in and user has ability to customize and export the report as a PDF. Added the ability to send a generated PDF directly to a user's OIS. *(Substantially equivalent to Predicate)*	Reporting built-in and user has ability to customize	Reporting built-in and user has ability to customize

7. Performance Data

As with the Predicate Device, no clinical trials were performed for ClearCalc. 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 ClearCalc were validated against accepted results for known planning parameters from clinically-utilized treatment planning systems. Electronic portal dosimetry quality assurance results compared a 2D array of TPS planned dose values to the

corresponding electronic portal dosimetry planar array using 3%/3mm criteria for both absolute and relative dosimetry to yield a 3D gamma analysis result. All passing criteria for ClearCalc's dose calculation algorithms (FSPB for photon plans, TG-71 for electron plans, TG-43 for brachytherapy plans, as well as Monte Carlo calculations for photons, electrons, and protons) remain consistent with the Predicate Device. These tests all passed regression testing.

8. Conclusion

ClearCalc Model RADCA V2.6 is deemed to be substantially equivalent to the scope of Predicate Device, ClearCalc Model RADCA V2 (K220582). Additional functionality was supported with comparison to the Reference Device SunCHECK (K170307). Verification and validation testing, and our risk documentation, demonstrate that ClearCalc is as safe and effective as the Predicate Device. The minor technological differences between ClearCalc Model RADCA V2.6 and the Predicate Device do not raise any questions on the safety and effectiveness of the Subject Device.