Radformation, Inc.
℅ Kurt Sysock
Co-founder/CEO
335 Madison Avenue, 4th floor
NEW YORK NY 10017

Re: K220582
Trade/Device Name: ClearCalc Model RADCA V2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: July 18, 2022
Received: July 21, 2022

Dear Kurt 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for

Julie Sullivan, Ph.D.
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

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)*

K220582

Device Name
ClearCalc Model RADCA V2

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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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	8/21/2022

5.2. Device Information

Table 2 : Device Information	
Trade Name:	ClearCalc Model RADCA V2
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

5.3. Predicate Device and Reference Device Information

Primary Predicate Device
ClearCalc Model RADCA V2 (Subject Device) makes use of its prior submission - ClearCalc Model RADCA (K193640) - as the primary Predicate Device.

Reference Devices
With the additions included in the submission, ClearCalc Model RADCA V2 also makes use of RadCalc Version 7.1 (K193381) and myQA iON (K201798) as Reference Devices for the new functionality.

5.4. Device Description

The ClearCalc Model RADCA V2 device is software that uses treatment data, image data, and structure set data obtained from 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.

5.5. 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.

5.6. Technological Characteristics

Predicate Device
ClearCalc Model RADCA V2 (Subject Device) makes use of its prior submission - ClearCalc Model RADCA (K193640) - as the Predicate Device. The functionality and technical components of this prior submission remain unchanged in ClearCalc Model RADCA V2. This submission is intended to build on the functionality and technological components of the 510(k) cleared ClearCalc Model RADCA.

Similar to the Predicate Device software, ClearCalc Model RADCA V2 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 (the same finite-size pencil beam algorithm as with the Predicate Device) or now optionally call a monte carlo dose calculation engine to perform dose and/or MU calculations. Though the monte carlo dose calculation

engine is new functionality, it serves the same purpose as the currently-implemented Finite-Size Pencil Beam (FSPB) algorithm and is launched from the local User Interface (UI). Additionally, this new algorithm is a monte carlo-based calculation, which is the “gold standard” for radiotherapy treatment planning and can improve the accuracy of the results provided by ClearCalc.

Additionally, new input files are being supported with the Subject Device, namely machine treatment log files and virtual source models. Machine log files record the precise machine parameter setting of linear accelerator deliveries during a set treatment delivery. These files record parameters similar to the treatment plan except they are recorded from a pre-treatment delivery at the machine instead of from a Treatment Planning System. Instead of using the treatment planning parameters, ClearCalc will use the delivered treatment parameters from the machine to re-calculate the dose from the given plan. Since the parameters in machine treatment log files are nearly identical to those captured in a treatment plan, this functionality does not raise any new questions in terms of safety and effectiveness compared to the predicate. The virtual source models are used by the monte carlo dose calculation engine to complete calculations and do not affect the current technological functionality when compared to the Predicate Device. Virtual source models are a different way to store pertinent beam data for dose calculation and originate from the beam data already stored in the Predicate Device. As such, they do not raise any new concerns regarding the safety or effectiveness of the Subject Device compared to the predicate.

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

Table 3: Substantial Equivalence ClearCalc Model RADCA V2 vs. Predicate Device and Reference Devices

Parameters	Subject Device: ClearCalc Model RADCA V2	Predicate Device: ClearCalc Model RADCA	Reference Device: RadCalc Version 7.1 (K193381)	Reference Device: myQA iON (K201798)
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)*	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.	A means of validating the monitors units or radiation dose to points that have been calculated by the primary radiation therapy planning system for external beam radiation therapy and/or brachytherapy treatments. In addition to this,	To perform patient quality assurance activities for radiation therapy treatment delivery systems. myQA iON is a software toolbox allowing the Medical Physicist to perform quality assurance activities before and after the

			RadCalc Software can also be used as the primary means of calculating monitor units for external beam radiation treatments in situations where the physician does not order the use of a radiation therapy plan. Users may also send/receive results from an eternal dose calculation engine, whereby the results are displayed in RadCalc for evaluation.	patient treatment fractions for all patients undergoing radiation therapy.
Energy Used and/or Delivered	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients. *(Substantially equivalent)*	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	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 *(Substantially equivalent)*	Trained radiation oncology personnel	Trained radiation oncology personnel	Trained radiation oncology health professionals
OTC/Rx	Rx *(Substantially equivalent)*	Rx	Rx	Rx
Design: Graphical User Interface	Contains a Data Visualization / Graphical User Interface *(Substantially Equivalent)*	Contains a Data Visualization / Graphical User Interface	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	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Files containing Structure Set, and Treatment Plan (including treatment field parameters) data	Files containing Structure Set, and Treatment Plan (including treatment field parameters) data as well as machine treatment log files

	machine treatment log files *(Substantially equivalent)*			
Design: Reporting and data routing	Reporting built-in and user has ability to customize *(Substantially equivalent)*	Reporting built-in and user has ability to customize	Reporting built-in and user has ability to customize	Reporting built-in and user has ability to customize
ClearCalc vs. Predicate Devices **Photon** MU and Dose Calculation				
Input	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data *(Substantially equivalent)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Files containing Structure Set, and Treatment Plan (including treatment field parameters) data	N/A
Functionality	Utilizes a Finite-Size Pencil Beam (FSPB) algorithm to calculate MU/Dose on a per-field basis.ClearCalc utilizes the full 3D geometry of the patient for heterogeneity corrections and simulating the scatter conditions of the actual patient. Users may also send/receive data from its monte carlo dose calculation engine (branded as RadMonteCarlo), whereby the results are displayed in ClearCalc for evaluation. *(Substantially equivalent)*	Utilizes a Finite-Size Pencil Beam (FSPB) algorithm to calculate MU/Dose on a per-field basis.ClearCalc utilizes the full 3D geometry of the patient for heterogeneity corrections and simulating the scatter conditions of the actual patient.	Utilizes a Clarkson summation algorithm to calculate MU/Dose on a per-field basis. RadCalc utilizes a consistent flat phantom geometry using radiological equivalent depth for heterogeneity corrections and includes modules that allow the user to indicate changes in scatter conditions (e.g. for breast treatments). Users may also send/receive results from an eternal dose calculation engine, whereby the results are displayed in RadCalc for evaluation.	N/A
Output	ClearCalc calculates the dose from fields	ClearCalc calculates the	RadCalc calculates the dose from fields	N/A

	in a plan and displays results for per-field MU and provides a difference metric for evaluation in tabular format. Users can also evaluate global point doses, as well as per-field doses and, when applicable, a generated dose volume histogram.. *(Substantially equivalent)*	dose from fields in a plan and displays results for per-field MU and provides a difference metric for evaluation in tabular format. Users can also evaluate global point doses, as well as per-field doses.	in a plan and displays results for per-field MU and provides a difference metric for evaluation in tabular format. Users can also evaluate global point doses, as well as per-field doses.	
ClearCalc vs. Predicate Devices **Electron** MU and Dose Calculation				
Input	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data *(Substantially equivalent)*	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Files containing Treatment Plan (including treatment field parameters) data	N/A
Functionality	Utilize a library of custom cutouts and computes cutout factors using a sector integration method. Cutout factors may also be user-entered. Users may also send/receive results from its monte carlo dose calculation engine (branded as RadMonteCarlo), whereby the results are displayed in ClearCalc for evaluation. *(Substantially equivalent)*	Utilize a library of custom cutouts and computes cutout factors using a sector integration method. Cutout factors may also be user-entered.	Utilize a library of custom cutouts and computes cutout factors using a sector integration or square root method. Cutout factors may also be user-entered. Users may also send/receive results from an eternal dose calculation engine, whereby the results are displayed in RadCalc for evaluation.	N/A
Output	ClearCalc calculates dose based on electron field	ClearCalc calculates dose based on electron	RadCalc calculates dose based on electron field	N/A

	parameters and cutout geometry, and displays results for per-field MU and/or dose and provides a difference metric for evaluation in tabular format and, when applicable, a generated dose volume histogram. *(Substantially equivalent)*	field parameters and cutout geometry, and displays results for per-field MU and/or dose and provides a difference metric for evaluation in tabular format.	parameters and cutout geometry, and displays results for per-field MU and/or dose and provides a difference metric for evaluation in tabular format.	
ClearCalc vs. RadCalc **Brachytherapy** Dose Calculation				
Input	Files or Treatment Planning System API-provided data containing Treatment Plan (including source positions and dwell times) data *(Substantially equivalent)*	Files or Treatment Planning System API-provided data containing Treatment Plan (including source positions and dwell times) data	Files containing Treatment Plan (including source positions and dwell times) data	N/A
Functionality	Utilizes the AAPM TG-43 protocol for its brachytherapy dose calculations *(Substantially equivalent)*	Utilizes the AAPM TG-43 protocol for its brachytherapy dose calculations	Utilizes the AAPM TG-43 protocol for its brachytherapy dose calculations	N/A
Output	ClearCalc calculates dose to arbitrary calculation point locations and presents difference metrics comparing the TPS dose vs. ClearCalc dose in a tabular format. *(Substantially equivalent)*	ClearCalc calculates dose to arbitrary calculation point locations and presents difference metrics comparing the TPS dose vs. ClearCalc dose in a tabular format.	RadCalc calculates dose to arbitrary calculation point locations and presents difference metrics comparing the TPS dose vs. RadCalc dose in a tabular format.	N/A
Parameters	**Subject Device: ClearCalc Model RADCA V2**	**Predicate Device: ClearCalc Model RADCA**	**Predicate Device: RadCalc Version 7.1 (K193381)**	**Predicate Device: myQA iON (K201798)**
ClearCalc vs. myQA iON **Proton** MU and Dose Calculation				
Input	Files/Treatment Planning System	N/A	N/A	Files containing Structure Set, and

	API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data *(Minor differences)*			Treatment Plan (including treatment field parameters) data
Functionality	Sends/receives data from its monte carlo dose calculation engine (branded as RadMonteCarlo) to calculate proton plans from the necessary files and displays the results to the user. *(Substantially equivalent)*	N/A	N/A	Sends/receives data from an external dose calculation engine to calculate proton plans from the necessary files and displays the results to the user.
Output	ClearCalc displays the dose results received from the RadMonteCarlo dose calculation engine and allows the user to analyze the results in the UI. *(Substantially equivalent)*	N/A	N/A	myQA iON displays the dose results received from the external dose calculation engine and allows the user to analyze the results in the UI.
ClearCalc vs. myQA iON **Machine Treatment Log File Analysis**				
Input	Files or Treatment Planning System API-provided data containing Treatment Plan data as well as machine log files from a pre-treatment or treatment session *(Substantially equivalent)*	N/A	N/A	Files containing Treatment Plan data as well as machine log files from a pre-treatment or treatment session
Functionality	Utilizes the machine logs files to reconstruct the delivered dose utilizing a dose calculation from the set machine parameters.	N/A	N/A	Utilizes the machine logs files to reconstruct the delivered dose utilizing a dose calculation from the set machine parameters.

	(Substantially equivalent)			
Output	ClearCalc displays the log file calculation result to the user via displayed dose information and provides a difference metric for evaluation. *(Substantially equivalent)*	N/A	N/A	myQA iON displays the log file calculation result to the user via displayed dose information and provides a difference metric for evaluation.

5.7. Performance Data

As with the Predicate Device and Reference Devices, 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. All passing criteria for ClearCalc's primary dose calculation algorithms (FSPB for photon plans, TG-71 for electron plans, and TG-43 for brachytherapy plans) remain consistent with the Predicate Device. Passing criteria for monte carlo calculations was a gamma analysis passing rate of >93% with +/-3% relative dose agreement and 3mm distance to agreement (DTA). The verification and validation testing passed in all test cases.

5.8. Conclusion

ClearCalc Model RADCA V2 is deemed substantially equivalent to the scope of Predicate Device, ClearCalc Model RADCA (K193640). Additional functionality for monte carlo calculations was supported with Reference Device RadCalc Version 7.1 (K1933981) and proton and machine treatment log file analysis for photons functionality was demonstrated with Reference Device myQA iON (K201798). Verification and Validation testing and the Risk Management Report demonstrate that ClearCalc is as safe and effective as the Predicate Device and Reference Devices. The minor technological differences between ClearCalc and the Predicate Device and Reference Devices do not raise any questions on the safety and effectiveness of the Subject Device.