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

Re: K220583
Trade/Device Name: ClearCheck Model RADCC V2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 20, 2022
Received: July 22, 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)*

K220583

Device Name
ClearCheck

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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	**08/23/2022**

5.2. Device Information

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

5.3. Predicate Device Information

Primary Predicate Device
ClearCheck Model RADCC V2 (Subject Device) makes use of its prior submission - ClearCheck Model RADCC (K162468) - as the Primary Predicate Device.

Secondary Predicate Device
With the addition of the Collision Check module included in the submission, ClearCheck Model RADCC V2 also makes use of CollisionCheck Model RADCO (K171350) as a Secondary Predicate Device for the additional functionality.

5.4. Device Description

The ClearCheck Model RADCC 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 present radiotherapy treatment plans in a user-friendly way for user approval of the treatment plan. The ClearCheck device (Model RADCC V2) is also intended to assist users to identify where collisions between the treatment machine and the patient or support structures may occur in a treatment plan.

It is designed to run on Windows Operating Systems. ClearCheck Model RADCC V2 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.

5.5. 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.

5.6. Technological Characteristics

Primary Predicate Device
ClearCheck Model RADCC V2 (Subject Device) makes use of its prior submission - ClearCheck Model RADCC (K162468) - as the Primary Predicate Device.

The functionality and technical components of this prior submission remain unchanged in ClearCheck Model RADCC V2. This submission is intended to build on the functionality and technological components of the 510(k) cleared ClearCheck Model RADCC.

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 and 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.

The submission for ClearCheck Model RADCC V2 contains additional functionality to assist in the plan generation process. The significant changes to the previously cleared devices (Primary and Secondary Predicates) are:

1. Prescriptions may be entered and managed within the software.
2. Radiation dose may be evaluated on different image sets through the use of a deformable registration object provided by Radformation's AutoContour Model RADAC V2 (K220598) software.
3. Biologically Equivalent Dose (BED) and Equivalent Dose in 2 Gy fractions (EQD2) may be evaluated for plans and plan sums.
4. Additional Dose Constraints and Plan Checks added.
5. Addition of a Collision Check module that alerts the user to a potential collision between the treatment machine and the patient or support structures. The Secondary Predicate Device is now included in the Subject device with additional features as stated below.
6. Additional reporting features.

Secondary Predicate Device

ClearCheck Model RADCC V2 (Subject Device) also makes use of CollisionCheck Model RADCO (K171350) as a Secondary Predicate Device for the additional functionality of the Collision Check module.

The Collision Check module within ClearCheck Model RADCC V2 is an updated version of the previously cleared CollisionCheck Model RADCO device. The core functionality of the Collision Check module is the same as in the Secondary Predicate Device, however additional features have been added. Treatment device components such as gantry head, SRS cones and Electron cones are modeled in the same way as they are in the Secondary Predicate Device. Similarly, SUPPORT, BOLUS and patient EXTERNAL structures are modeled in the same way as in the Secondary Predicate device. Collision calculations between the two classes of structures remain the same as in the Secondary Predicate Device, where a collision occurs if any part of a Treatment device component is found within a SUPPORT, BOLUS, or patient EXTERNAL structure for the particular

plan geometry. HU collisions are calculated in the same way as in the Secondary Predicate Device as well.

The added features to the Collision Check module in the Subject Device are as follows:

1. The ability to assess collisions with kV On Board Imaging arms (OBI)
2. The ability to detect collision warnings, i.e. situations where there is no collision detected but two objects are within a user defined warning distance of each other.
3. Sticky settings
4. Printing capabilities

Table 3: Substantial Equivalence ClearCheck Model RADCC V2 vs. Primary Predicate: ClearCheck Model RADCC (K162468) and Secondary Predicate: CollisionCheck Model RADCO (K171350)

Parameters	Subject Device: ClearCheck Model RADCC V2	Primary Predicate: ClearCheck Model RADCC (K162468)	Secondary Predicate: CollisionCheck Model RADCO (K171350)	Equivalence
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.	ClearCheck is intended for quality assessment of radiotherapy treatment plans	CollisionCheck is 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 Primary and Secondary Predicates
Energy Used and/or Delivered	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	None – software-only application. The software application does not deliver or depend on energy delivered to or from patients.	Equivalent to both Primary and Secondary Predicates

		patients.		
Intended users	Trained clinically qualified radiation oncology personnel	Trained clinically qualified radiation oncology personnel	Trained clinically qualified radiation oncology personnel	Equivalent to both Primary and Secondary Predicates
OTC/Rx	Rx	Rx	Rx	Equivalent to both Primary and Secondary Predicates
Functionality	Performs dosimetric and plan evaluation for Radiation Treatment Plans. Also simulates the plan and predicts whether that no gantry collisions occur with patient or support structures	Performs dosimetric and plan evaluation for Radiation Treatment Plans.	Simulates the plan and predicts whether any gantry collisions occur with patient or support structures.	Equivalent to both Primary and Secondary Predicates
Design: Graphical User Interface	Contains a Data Visualization / Graphical User Interface	Contains a Data Visualization / Graphical User Interface	Contains a Data Visualization / Graphical User Interface	Equivalent to both Primary and Secondary Predicates
Design: Supported Files	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Equivalent to both Primary and Secondary Predicates
Design: Calculation Requirements	Uses local hardware	Uses local hardware	Uses local hardware	Equivalent to both Primary and Secondary Predicates
Design: Reporting	Reporting built-in and user has ability to customize	Reporting built-in and user has ability to customize	No reporting capabilities	Equivalent to Primary Predicate
Pure software	Yes	Yes	Yes	Equivalent to both Primary

				and Secondary Predicates
Operating System	Windows Operating System	Windows Operating System	Windows Operating System	Equivalent to both Primary and Secondary Predicates
Input	Treatment data, image data, and structure set data obtained from supported Treatment Planning System and Application Programming interfaces	Treatment data, image data, and structure set data obtained from supported Treatment Planning System and Application Programming interfaces	Treatment data, image data, and structure set data obtained from supported Treatment Planning System and Application Programming interfaces	Equivalent to both Primary and Secondary Predicates
ClearCheck Model RADCC V2 vs. ClearCheck Model RADCC (K162468) Functionality Comparison				
Dose Constraints	Additional dose constraints added	Initial set of dose constraints	N/A	Minor differences with Primary Predicate
Plan Checks	Additional plan checks added	Initial set of plan checks	N/A	Minor differences with Primary Predicate
Create Users and Edit User Rights	Addition of option to authenticate with Active Directory credentials	User rights managed by Administration Application	N/A	Minor differences with Primary Predicate
Global and Patient Specific Templates	Addition of Prescription templates and overall improvements to template usability	Initial set of dose constraint and plan check templates	N/A	New Feature / Minor differences with Primary Predicate
Reporting	Improvements to report usability	Initial reporting functionality	N/A	Minor differences with Primary Predicate
Compare Treatment Plans	Improvements to plan comparison usability	Initial plan comparison functionality	N/A	Minor differences with Primary Predicate

Prescription	Physician prescriptions may be entered and managed in the ClearCheck software.	N/A	N/A	New Feature
Deformed Dose Evaluation	Radiation dose may be evaluated on different image sets through the use of a deformable registration object.	N/A	N/A	New Feature
BED/EQD2 dose	Ability to evaluate BED/EQD2 for plans and plan sums	N/A	N/A	New Feature
ClearCheck Model RADCC V2 vs. CollisionCheck Model RADCO (K171350) Functionality Comparison				
Parameters	**Subject Device: ClearCheck** Model **RADCC V2**		**Secondary Predicate: CollisionCheck (K171350)**	**Equivalence**
Simulation Details	Simulates the plan and predicts whether any gantry collisions occur with patient or support structures. Calculates gantry clearance by modeling the linac as a cylinder with a user-configured value for distance between isocenter and the face of the gantry. Collision Check also supports additional applicators: Stereotactic radiosurgery cones (also modeled as a cylinder) and Electron Applicators (modeled as a rectangular prism). ClearCheck also simulates the on-board imaging (OBI) arms as a rectangular prism. User can define a	N/A	Simulates the plan and predicts whether any gantry collisions occur with patient or support structures. Calculates gantry clearance by modeling the linac as a cylinder with a user-configured value for distance between isocenter and the face of the gantry. CollisionCheck also supports additional applicators: Stereotactic radiosurgery cones (also modeled as a cylinder) and Electron Applicators (modeled as a rectangular prism).	Minor differences with Secondary Predicate

	warning distance that adds a margin to the shapes in the simulation.			
Collision Check Output	Collision Check tests thousands of sample points against CT data and patient and couch structures and reports the number of sample points that resulted in a collision. Collision Check also displays these sample point test results with a 3D display and an axial 2D image plane viewer for the user to inspect the results. If the user has defined warning distances, then collisions within the warning margin are presented to the user with a different color and label.	N/A	CollisionCheck tests thousands of sample points against CT data and patient and couch structures and reports the number of sample points that resulted in a collision. CollisionCheck also displays these sample point test results with a 3D display and an axial 2D image plane viewer for the user to inspect the results.	Minor differences with Secondary Predicate

5.7. Performance Data

As with the Primary and Secondary Predicates, no clinical trials were performed for ClearCheck Model RADCC V2. Verification tests were performed to ensure that the software works as intended and pass/fail criteria were used to verify requirements.

Validation testing for the added BED / EQD2 functionality compared ClearCheck's results on a plan and plan sum against values calculated by hand using the well-known BED / EQD2 formulas. A passing criteria of 0.5% difference for dose type constraints and 3% for Volume type constraints was used. Validation testing for the added Deformed

Dose functionality compared known dose deformations to the deformed dose results from ClearCheck. Qualitative dose-volume histogram (DVH) analysis showed good agreement for all cases and evaluation of D_{mean} and D_{max} differences used a quantitative +/-3% difference to achieve a passing result. The verification and validation testing passed in all test cases.

5.8. Conclusion

ClearCheck Model RADCC V2 is substantially equivalent to the Primary Predicate Device, ClearCheck Model RADCC (K162468). Additionally, the Collision Check module found within ClearCheck Model RADCC V2 is substantially equivalent to the Secondary Predicate Device, CollisionCheck Model RADCO (K171350). The minor technological differences between ClearCheck and the Primary and Secondary Predicate Devices do not raise any questions on the safety and effectiveness of the Subject Device. Verification and Validation testing and the Risk Management Report demonstrate that the ClearCheck is as safe and effective as the Primary and Secondary Predicates.