January 5, 2026

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

Re: K252988
Trade/Device Name: ChartCheck (RADCH V1.6)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: September 17, 2025
Received: September 18, 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

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.	K252988

Please provide the device trade name(s).

ChartCheck (RADCH V1.6)

Please provide your Indications for Use below.

ChartCheck is intended to assist with the quality assessment of radiotherapy treatment plans and on treatment review.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

RAD formation

K252988

510(k) Summary - ChartCheck (RADCH V1.6)

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:	Kevin Robinson
Company:	Radformation, Inc.
Address:	261 Madison Avenue, 9th Floor New York, NY 10016
Contact Person:	Kevin Robinson VP of Regulatory Affairs, Radformation
Phone:	585-500-6996
Fax:	---------
Email:	krobinson@radformation.com
Date of Summary Preparation	9/17/2025

2. Device Information

Table 2 : Device Information	
Trade Name:	ChartCheck (RADCH V1.6)
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 Information

ChartCheck (RADCH V1.6) (Subject Device) makes use of its prior submission ChartCheck (K201119) as the Predicate Device.

Reference Devices

With the additions included in the submission, ChartCheck (RADCH V1.6) also makes use of ClearCheck (K220583), ClearCalc (K220582), AutoContour (K242729), and Velocity (K173636) as Reference Devices for new evaluation and synthetic image functionality.

4. Device Description

The ChartCheck device is software that enables trained radiation oncology personnel to perform quality assessments of treatment plans and treatment chart reviews utilizing plan, treatment, imaging, as well as documentation data obtained from an Oncology Information System database(s).

ChartCheck contains 3 main components:

a. An agent service that is configured by the user to monitor an Oncology Information System (OIS) database. The agent watches for new treatment plans, treatment records, documentation, and images. The agent uploads data to a checking service.
b. A checking service that compares the treatment records to the treatment plan and calculates check states as new records are uploaded from the agent. The checking service processes on-treatment imaging data and interfaces with outside software platforms for dose calculation activities.
c. A web application accessed via a web browser that contains several components.
    i. Chart checking mode, which allows a medical physicist to review treatment records and check state results, record chart check comments, and mark the chart check as approved.
    ii. An image viewer that allows a medical physicist to review on-treatment imaging, on-treatment dose calculation results, and perform deformable registration editing.
    iii. Settings mode, which allows an administrator to set check state colors, configure settings, define check state templates, set up check alerts, documentation generation, and billing settings.

5. Indications for Use

ChartCheck is intended to assist with the quality assessment of radiotherapy treatment plans and on treatment review.

6. Technological Characteristics

Predicate Device

ChartCheck (RADCH V1.6) vs. ChartCheck (K201119)

ChartCheck (RADCH V1.6) (Subject Device) makes use of its prior submission - ChartCheck (K201119) - as the Predicate Device. The similar Indications for Use, patient population, functionality, and technical components of this Predicate Device remain unchanged in ChartCheck (RADCH V1.6). 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 ChartCheck device.

As with the Predicate Device, ChartCheck (RADCH V1.6) is designed to run on Windows Operating Systems and is utilized for on-treatment review of radiotherapy treatment plans to ensure treatments are proceeding as prescribed. New functionality is added that allows for more on treatment review functionality by generating synthetic images, for example, from the on-treatment images (CBCT) and the original planning CT, calculating doses for each fraction on the latest synthetic images, and displaying results of the assigned treatment planning dose constraint objectives. With this new functionality, there are a few added UI components in order to display the new information.

Reference Device Comparison

ChartCheck (RADCH V1.6) vs. ClearCheck Model RADCC V2 (K220583)
ChartCheck (RADCH V1.6) includes new functionality to utilize treatment planning dose constraint objectives to calculate on-treatment doses and determine if they meet the original planning objectives. Reference Device ClearCheck (K220583) already includes the functionality to leverage a template-based dose constraint objective list to determine if these planning objectives are met with the provided dose information. ClearCheck also allows the user to import and visualize registration information, including deformed dose, leveraging these registrations. ChartCheck (RADCH V1.6) utilizes the same methods and libraries cleared under ClearCheck (K220583) to perform the on-treatment dose constraint objectives and visualize results.

ChartCheck (RADCH V1.6) vs. ClearCalc Model RADCA V2 (K220582)
ChartCheck (RADCH V1.6) includes new functionality to utilize machine treatment log files to calculate on-treatment doses. Reference Device ClearCalc (K220582) already includes the functionality to leverage its Monte Carlo algorithm, RadMonteCarlo, to calculate doses using machine treatment log files. ChartCheck (RADCH V1.6) utilizes the same methods and libraries cleared under ClearCalc (K220582) to perform the on-treatment calculations and visualize results.

ChartCheck (RADCH V1.6) vs. AutoContour Model RADAC V4 (K242729)
ChartCheck (RADCH V1.6) includes new functionality to utilize image registrations, including deformable, to generate a synthetic CT from the on-treatment images and the treatment planning CT(s). Reference Device AutoContour (K242729) already includes the ability to perform rigid and deformable registrations. AutoContour also allows the user to visualize and edit registrations. ChartCheck (RADCH V1.6) utilizes the same methods and libraries cleared

under AutoContour (K242729) to perform the on-treatment registration and to visualize and edit results.

ChartCheck (RADCH V1.6) vs. Velocity (K173636)

Varian Medical System's Velocity software is summarized as "Velocity is a software application providing relevant tools for Radiotherapy professionals to use while creating treatment plans. The Velocity device is a Picture Archiving and Communication System (medical imaging software). Velocity provides medical image processing designed to facilitate the oncology or other clinical specialty workflow by allowing the comparison of medical imaging data from different modalities, points in time, and/or scanning protocols. The product provides users with the means to display, co-register and analyze medical images from multiple modalities including PET, SPECT, CT, RT Dose and MR; draw Regions of Interest (ROI), calculate and report relative differences in pixel intensities, Standardized Uptake Value (SUV) or other values within those regions; and import/export results to/from commercially available radiation treatment planning systems and PACS devices. Co-registration includes deformable registration technology that can be applied to DICOM data, including diagnostic and planning image volumes, structures, dose, and automatic anatomical atlas-based segmentation tools." (https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173636.pdf - accessed 9/15/2025)

ChartCheck (RADCH V1.6) includes new functionality to generate synthetic images from the on-treatment images and the treatment planning images. Reference Device Velocity (K173636) already includes the ability to perform rigid and deformable registrations as well as generate synthetic images from the on-treatment and planning images, such as CBCT and CT. ChartCheck (RADCH V1.6) builds upon the registration functionality of AutoContour (K242729) to generate synthetic images similar to the already cleared Velocity (K173636) functionality.

Table 3: Substantial Equivalence ChartCheck (RADCH V1.6) vs. Predicate Device and Reference Devices						
Parameters	**Subject Device: ChartCheck (RADCH V1.6)**	**Predicate Device: ChartCheck (K201119)**	**Reference Device: ClearCheck Model RADCC V2 (K220583)**	**Reference Device: ClearCalc Model RADCC V2 (K220582)**	**Reference Device: AutoContour Model RADAC V4 (K242729)**	**Reference Device: Velocity (K173636)**
Summarized Indications for use	ChartCheck is intended to assist with the quality assessment of radiotherapy treatment plans and on-treatment review. *(Substantially equivalent to Predicate)*	The ChartCheck device is intended for the quality assessment of radiotherapy treatment plans and on-treatment chart review.	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.	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.	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.	Velocity is a software package that provides physicians a means for comparison of medical data, including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning, and other medical specialties. Velocity is not intended for mammography.
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	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 *(Equivalent to Predicate)*	Trained radiation oncology personnel	Trained radiation oncology personnel	Trained radiation oncology personnel	Trained radiation oncology personnel	Diagnostic radiology, oncology, radiation therapy planning, and other medical specialties
OTC/Rx	Rx *(Equivalent to Predicate)*	Rx	Rx	Rx	Rx	Rx

7. Performance Data

As with the predicate device, no clinical trials were performed for ChartCheck (RADCH V1.6). Verification testing was conducted to ensure that the software functions as intended, and predefined pass/fail criteria were used to verify compliance with software requirements. Patient chart parameters in ChartCheck were validated against known outputs from supported record and verify systems. SyntheticCT (Structure, registration, and dose) algorithm outputs were validated through comparative testing against established reference systems. These comparisons verified that equivalent inputs produced consistent and expected outputs across systems, thereby confirming the correctness of algorithm performance. These verification and validation activities demonstrate that ChartCheck (RADCH V1.6) meets its design requirements, performs as intended, and is suitable for its intended use.

8. Conclusion

ChartCheck (RADCH V1.6) is deemed substantially equivalent to the Predicate Device, ChartCheck (K201119). Verification tests were performed to ensure that the software works as intended, and pass/fail criteria were used to verify requirements. Verification testing was performed to ensure that the software was behaving as intended, and output results from ChartCheck were validated against accepted results for known planning parameters from clinically-utilized treatment planning systems. Functional and regression testing passed. Our Verification and Validation testing and risk documentation all demonstrate that ChartCheck is as safe and effective as the Predicate Device. The minor technological differences between ChartCheck (RADCH V1.6) and the Predicate Device do not raise any significant questions on the safety and effectiveness of the Subject Device.