Radformation, Inc.
% Mr. Kurt Sysock
Co-founder/CEO
335 Madison Avenue, 16th Floor
NEW YORK NY 10017

June 26, 2020

Re: K201119
Trade/Device Name: ChartCheck
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 21, 2020
Received: April 27, 2020

Dear Mr. 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201119

Device Name
ChartCheck

Indications for Use *(Describe)*

The ChartCheck device is intended for the quality assessment of radiotherapy treatment plans and on treatment chart review.

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

K201119

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	04/20/2020

5.2. Device Information

Table 2 : Device Information	
Trade Name:	ChartCheck
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

5.3. Predicate Device Information

ARIA Radiation Therapy Management (K173838)

5.4. Device Description

The ChartCheck device is software that enables trained radiation oncology personnel to perform quality assessments of treatment plans and treatment chart review utilizing plan, treatment, imaging, and documentation data obtained from the ARIA Radiation Therapy Management database.

ChartCheck contains 3 main components:

1. An agent service that is configured by the user to monitor their ARIA Radiation Therapy Management database. The agent watches for new treatment plans, treatment records, documentation, and imaging data. The agent uploads new data to the cloud based checking service.
2. A cloud based checking service calculates check states as new records are uploaded from the agent.
3. A web application accessed via a web browser which contains several components.
    a. It allows trained radiation oncology personnel to review treatment records, view the check state calculation results, record comments,, and mark the chart checks as approved.
    b. It allows an administrator to set check state colors, configure default settings, and define check state logic.

5.5. Indications for Use

The ChartCheck device is intended for the quality assessment of radiotherapy treatment plans and on treatment chart review.

5.6. Technological Characteristics

ChartCheck (Subject Device) makes use of a Predicate Device, ARIA Radiation Therapy Management (K173838) for substantial equivalence comparison.

5.6.1. ChartCheck vs. ARIA Radiation Therapy Management (K173838)

Varian's ARIA Radiation Therapy Management software "is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Therapy Management also stores the treatment histories including dose delivered to defined sites, and provides tools to verify performed treatments." (https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173838.pdf accessed 04/17/2020)

ChartCheck contains a subset of the features found in ARIA Radiation Therapy Management. ChartCheck provides tools to verify treatment plans and treatments utilizing the same treatment data used by ARIA Radiation Therapy Management. The software is very similar in design and function to the ARIA Radiation Therapy Management software, particularly the "ChartQA" module.

Table 3: Substantial Equivalence ChartCheck vs. ARIA Radiation Therapy Management			
Parameters	Subject Device: ChartCheck Radformation	Predicate Device: ARIA Radiation Therapy Management (K173838)	Equivalence
Indications for use	The ChartCheck device is intended for the quality assessment of radiotherapy treatment plans and on treatment chart review.	The ARIA Radiation Therapy Management product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Therapy Management also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments.	Substantially Equivalent
Pure software	Yes	Yes	Equivalent
Intended users	Trained radiation oncology personnel	Trained radiation oncology personnel	Equivalent
OTC/Rx	Rx	Rx	Equivalent
ChartCheck vs. ARIA Radiation Therapy Management			
Input	Treatment planning, treatment, imaging, and documentation data from the ARIA Radiation Therapy Management database.	DICOM treatment records and images from radiation therapy machines. User-entered treatment documentation	Equivalent
Functionality	Utilizes treatment, treatment planning, imaging, and documentation data to calculate pass / fail / override / condition check states	Utilizes treatment and treatment planning data to calculate pass / fail / override check states	Substantially Equivalent
Output	ChartCheck displays treatment and planned values along with check state indicators. ChartCheck presents control charts	ARIA Radiation Therapy Management displays treatment and planned values along with check state indicators. ARIA Radiation Therapy Management presents control charts	Substantially Equivalent

5.7. Performance Data

As with the Predicate Device, no clinical trials were performed for ChartCheck. Verification tests were performed to ensure that the software works as intended and pass/fail criteria were used to verify requirements.

5.8. Conclusion

ChartCheck is deemed substantially equivalent to the Predicate Device, ARIA Radiation Therapy Management (K173838). The fact that ChartCheck indications for use are a subset of the predicate device's indications for use does not raise any new questions regarding safety and effectiveness. Verification and Validation testing and Hazard Analysis demonstrate that ChartCheck is as safe and effective as the Predicate Device.