November 29, 2017

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

Re: K171350
Trade/Device Name: CollisionCheck
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 4, 2017
Received: October 11, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171350/S001

Device Name
CollisionCheck

Indications for Use *(Describe)*
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.

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.

3.1. 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	05/01/2017

3.2. Device Information

Table 2 : Device Information	
Trade Name:	CollisionCheck
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

3.3. Predicate Device Information

Mobius3D (K153014)

3.4. Device Description

The CollisionCheck device (model RADCO) is software intended to assist users to identify where collisions between the treatment machine and the patient or support structures may occur in a treatment plan. The treatment plans are obtained from the Eclipse Treatment Planning System (also referred to as Eclipse TPS) of Varian Medical Systems. CollisionCheck runs as a dynamic link library (DLL) plugin to Varian Eclipse.

It is designed to run on the Windows Operating System. CollisionCheck performs calculations on the plan obtained from Eclipse TPS (Version 12 (K131891), Version 13.5 (K141283), and Version 13.7 (K152393) which is a software used by trained medical professionals to install and simulate radiation therapy treatments for malignant or benign diseases.

3.5. Indications for Use

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.

3.6. Technological Characteristics

CollisionCheck (Subject Device) makes use of a Predicate Device, Mobius3D (K153014) for substantial equivalence comparison.

3.6.1. CollisionCheck vs. Mobius3D (K153014)

Mobius3D provides the following feature (as described on the manufacturer's website at http://mobiusmed.com/mobius3d/ as of March 27, 2017):
"Deliverability Analysis: Confirm Before Your Patient Arrives. Mobius3D performs a virtual delivery of the plan and verifies that no gantry collision or violation of your machine's delivery parameters is predicted."

CollisionCheck likewise simulates the plan and verifies that no gantry (treatment machine) collisions occur. The main difference between the implementation of that feature by Mobius3D and CollisionCheck is that Mobius3D takes DICOM plan data as input in order to perform the virtual delivery while CollisionCheck obtains treatment plan information from the Varian Medical Systems Eclipse Treatment Planning System through its scripting API. Furthermore, CollisionCheck does not have any other features besides the gantry collision check while Mobius3D includes many other features that are not related to the gantry collision check.

From Mobius3D's Intended Use statement: "Mobius3D software is used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy." CollisionCheck is likewise a quality assurance and treatment plan verification tool, but one with the very specific scope of checking for potential treatment machine collisions that might occur in a treatment plan.

Table 3: Substantial Equivalence CollisionCheck vs. Mobius3D			
Parameters	Subject Device: CollisionCheck Radformation	Predicate Device: Mobius3D (K153014)	Equivalence
Indications for use	Used 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	Used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy.	Subject Device is a subset of the Predicate Device
Pure software	Yes	Yes	Equivalent
Intended users	Trained radiation oncology personnel	Trained radiation oncology personnel	Equivalent
OTC/Rx	Rx	Rx	Equivalent
CollisionCheck vs. Mobius3D Deliverability Analysis			
Input	CT, Structure Set, and Treatment Plan data accessed through the Eclipse Scripting API	DICOM files containing CT, Structure Set, and Treatment Plan (including treatment field parameters) data	Minor Differences
Functionality	Simulates the plan and predicts whether that no gantry collisions occur with patient or support structures.	Performs a virtual delivery of the plan and verifies that no gantry collision is predicted.	Equivalent
Simulation Details	CollisionCheck 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).	Mobius3D calculates gantry clearance in Plan Checks by modeling the linac as a cylinder with a user-configured value for distance between isocenter and the face of the gantry.	Minor Differences
Output	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	Mobius3D determines the closest distance between the treatment head and the patient/couch for each beam and displays a warning if this distance is <= 3cm and an alert if the clearance is <= 0cm.	Minor Differences

	with a 3D display and an axial 2D image plane viewer for the user to inspect the results.		

3.7. Differences Discussion

Indications for use

Mobius3D is a quality assurance platform that includes a wide variety of plan checks, including a collision check. CollisionCheck is highly specialized to only perform the collision check function, and therefore CollisionCheck performs only a subset of the uses provided by the predicate device Mobius3D. The fact that CollisionCheck performs only this specialized function does not raise any questions regarding safety and effectiveness in that this specialized function can stand alone and independent of all other functions contained in the Mobius3D predicate device.

Input

Mobius3D requires the CT, Structure Set, and Treatment Plan data to be exported from a treatment planning system in DICOM format. CollisionCheck obtains the same data directly from the Eclipse treatment planning system through Eclipse's Scripting API. This does not raise any new questions regarding safety and effectiveness in that, relative to DICOM export/import, the Eclipse Scripting API layer is closer to the original data and requires less manual user input, therefore exposing fewer issues associated with errors in the DICOM import/export process as well as user error in accidentally exporting or importing the wrong DICOM files.

Simulation Details

Mobius3D and CollisionCheck both simulate the gantry face and head as a cylinder, but CollisionCheck also supports the addition of applicators (which are mounted to the face of the gantry). These are simulated using simple geometries that are no more difficult to simulate than the cylinder used in the gantry face and therefore this difference does not raise new questions regarding safety and effectiveness. The simulation of stereotactic radiosurgery cones and electron applicators increases safety and effectiveness of the device by assisting the treatment planner to predict and avoid collisions with those applicators.

Output

Mobius3D determines the closest distance between the patient and support structures and the simulated gantry head and gives an alert or warning based on the result.

CollisionCheck tests not only patient and support structures for collisions (referred to in CollisionCheck as Structure-based Collisions) but also tests the simulated geometry against the Hounsfield-Unit CT data (referred to in CollisionCheck as HU-based Collisions) to report to the user the number and location of the sample points that resulted in either of those collisions. HU-based collision test adds an extra layer of safety in that the treatment setup, patient geometry, and support structures may not be fully

described by the structure set and by testing the HU values may detect a collision that would otherwise be missed if only the structure set is considered.

In addition to displaying the number of sample point collisions detected, CollisionCheck also displays a 3D model of the simulated treatment unit with the patient and support structure geometry that allows the user to visualize where the treatment unit will be in the treatment. This increases safety significantly in that Mobius3D and CollisionCheck both are limited in the accuracy of their collision check by the data available in the CT and structure set, and where patient anatomy falls outside of the bounds of that data, only manual inspection can determine whether there is a collision risk in those instances. The 3D display provided by CollisionCheck makes it significantly easier and more accurate to manually inspect the treatment geometry for these potential issues.

CollisionCheck also provides an 2D axial slice view of the collision check results which allows the user to see where the treatment machine will be for each treatment field within the actual CT data to assist the user in identifying exactly where the collisions would occur within the patient or support structures.

These differences in output do not raise any questions regarding the safety and effectiveness of CollisionCheck relative to the predicate device Mobius3D.

3.8. Performance Data

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

3.9. Conclusion

CollisionCheck is deemed substantially equivalent to the Predicate Device, Mobius3D (K153014) due to the similarities with the Mobius3D collision check feature. Verification and Validation testing and Hazard Analysis demonstrate that CollisionCheck is as safe and effective as the Predicate Device. The minor technological differences between CollisionCheck and the Predicate Device with regard to the shared gantry collision check feature do not raise any questions on the safety and effectiveness of the Subject Device.