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

April 9, 2020

Re: K193640
Trade/Device Name: ClearCalc
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: March 9, 2020
Received: March 9, 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)*

K193640

Device Name

ClearCalc

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.**

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

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# Section 5. 510(k) Summary

K193640

This 510(k) Sumary 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<br>New York, NY 10017 |
| Contact Person: | Alan Nelson<br>Chief Science Officer, Radformation |
| Phone: | 518-888-5727 |
| Fax: | --------- |
| Email: | anelson@radformation.com |
| Date of Summary Preparation | 12/20/2019 |

### 5.2. Device Information

| Table 2 : Device Information | |
|---|---|
| Trade Name: | ClearCalc |
| Common Name: | Oncology Information System |
| 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 Information

RadCalc: 510(k) Number K090531; Regulation number 892.5050; Product code: MUJ

### 5.4. Device Description

The ClearCalc device (model RADCA) is software intended to assist users in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation. The treatment plans are obtained from supported Treatment Planning System and Application Programming interfaces.

It is designed to run on the Windows Operating System. ClearCalc performs calculations on the treatment plan data obtained from supported Treatment Planning System and Application Programming interfaces. A Treatment Planning System is software used by trained medical professionals to install and simulate radiation therapy treatments for malignant or benign diseases.

### 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

ClearCalc (Subject Device) makes use of a Predicate Device, RadCalc (K090531) for substantial equivalence comparison.

#### 5.6.1. ClearCalc vs. RadCalc (K090531)

Lifeline Software, Inc.'s RadCalc Software "is a stand-alone program or operating from a server that provides determination of monitor units and/or the dose to various points of interest for external beam radiation therapy and/or brachytherapy treatments. RadCalc is designed to work on personal computers in a Windows operating system that is connected directly to the primary radiation therapy planning system. The program makes the task of performing independent Monitor Unit validations much faster, easier, and more accurate. RadCalc determines the monitor units or dose through the process of looking data up from previously input tables or data curves." (https://www.accessdata.fda.gov/cdrh_docs/pdf9/K090531.pdf accessed 12/17/2019)

ClearCalc likewise utilizes an independent calculation algorithm to recalculate the incoming treatment plan's MU and dose for external beam plans as well as dose from radioactive sources for brachytherapy plans. The software is very similar in design and function to the RadCalc software.

| Table 3: Substantial Equivalence ClearCalc vs. RadCalc | | | |
|---|---|---|---|
| Parameters | Subject Device: ClearCalc Radformation | Predicate Device: RadCalc (K090531) | Equivalence |
| Indications for use | Used to assist radiation treatment planners in determining if their treatment planning calculations are accurate using an independent Monitor Unit (MU) and dose calculation algorithm. | The intended use of the RadCalc Software is 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, 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. | Substantially Equivalent |
| Pure software | Yes | Yes | Equivalent |
| Intended users | Trained radiation oncology personnel | Trained radiation oncology personnel | Equivalent |
| OTC/Rx | Rx | Rx | Equivalent |
| ClearCalc vs. RadCalc **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 | Files containing Structure Set, and Treatment Plan (including treatment field parameters) data | Minor differences |
| Functionality | Utilizes a Finite-Size Pencil Beam (FSPB) algorithm to calculate MU/Dose on a per-field basis.<br>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.<br>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). | Minor differences |
| Output | ClearCalc calculates the dose from fields in a plan and displays results for per-field MU | RadCalc calculates the dose from fields in a plan and displays results for per-field MU and | Equivalent |

| | | | |
|---|---|---|---|
| | and provides a difference metric for evaluation in tabular format. Users can also evaluate global point doses, as well as per-field doses. | provides a difference metric for evaluation in tabular format. Users can also evaluate global point doses, as well as per-field doses. | |
| ClearCalc vs. RadCalc **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 | Files containing Treatment Plan (including treatment field parameters) data | Minor differences |
| Functionality | Utilize a library of custom cutouts and compute cutout factors using a sector integration method. | Utilize a library of custom cutouts and compute cutout factors using a sector integration or square root method. | Minor differences |
| Output | ClearCalc calculates dose based on electron field parameters and cutout geometry, and displays results for per-field MU and dose and provides a difference metric for evaluation in tabular format. | RadCalc calculates dose based on electron field parameters and cutout geometry, and displays results for per-field MU and dose and provides a difference metric for evaluation in tabular format. | Equivalent |
| 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 | Files containing Treatment Plan (including source positions and dwell times) data | Minor differences |
| Functionality | Utilizes the AAPM TG-43 protocol for its brachytherapy dose calculations | Utilizes the AAPM TG-43 protocol for its brachytherapy dose calculations | Equivalent |
| Output | 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 | Equivalent |

### 5.7. Performance Data

As with the Predicate Device, 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.

### 5.8. Conclusion

ClearCalc is deemed substantially equivalent to the Predicate Device, RadCalc (K090531). Verification and Validation testing and Hazard Analysis demonstrate that ClearCalc is as safe and effective as the Predicate Device. The minor technological differences between ClearCalc and the Predicate Device with regard to the independent MU and dose calculation do not raise any questions on the safety and effectiveness of the Subject Device.