LifeLine Software, Inc.
% Mr. Craig A. Laughton
Chief Executive Officer
3304 S Broadway Avenue, Suite 200
TYLER TX 75701

December 31, 2019

Re: K193381
Trade/Device Name: RadCalc Software, Version 7.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ, IYE
Dated: December 2, 2019
Received: December 5, 2019

Dear Mr. Laughton:

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)*
K193381

Device Name
RadCalc Software, Version 7.1

Indications for Use *(Describe)*
RadCalc has the following intended uses:

1. RadCalc performs a secondary dose calculation verification on the treatment plan done by the treatment planning software. This is RadCalc's primary function. Radiation therapy systems typically calculate the monitor units needed to deliver the desired amount of radiation to a point of reference within the patient. In this situation, RadCalc will serve to validate those monitor units computed by the primary radiation therapy planning system. Additional verification activities revolve around point dose comparisons, 3D dose evaluation via Gamma analysis, and DVH comparisons. It is not the intention of RadCalc to replace the calculation performed by the primary radiation therapy planning computer but to validate its calculation as a means of quality assurance. The practice of performing a secondary check is recommended by the American Association of Physicists in Medicine (AAPM) Task Group 40 as part of a good quality assurance program. This practice is an important aspect in providing quality patient care.

2. Import data from the treatment planning software and export the data from the treatment planning system to the verify and record system, which is the device that actually controls the radiation beam. This will reduce the number of errors that occur as a result of manually inputting this data.

3. In addition to performing the secondary dose verification calculation, RadCalc can also be used as the primary means of calculating monitor units in situations where the physician does not order the use of a radiation therapy treatment plan. RadCalc can independently calculate the amount of radiation the beam should produce (called the MU or monitor unit) to deliver to the patient the radiation dose the doctor recommends. This function is usually only used in urgent, emergency situations.

4. In addition, RadCalc performs brachytherapy-type calculations. For brachytherapy calculations, High Dose Rate (HDR), Low Dose Rate (LDR), and Permanent type treatments can be verified. Verification activities revolve around point dose comparisons, 3D dose evaluation via Gamma analysis, and DVH comparisons. RadCalc is not used as a primary means of calculating patient dose for brachytherapy treatments.
5. Analysis of fluence and dose maps can be performed via percentage difference, distance to agreement, or gamma analysis methodologies.

6. Interoperability with external dose calculation engines (EDCE) by sending them treatment plans and associated information in their necessary format so that the EDCE can perform a 3D dose calculation using its dose calculation algorithm. The computed dose volume is received back and the 3D analysis tools described above are used to compare against the treatment planning system.

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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