K090531

510(k) Summary

MAY 27 2009

For

RadCalc Software

1. Sponsor Information

LifeLine Software, Inc.
311 Hines Crossing
Bullard, TX 75757
Phone: (903) 207.4298 x13
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Contact: Craig Laughton, CEO

2. Applicant Information

Emergo Group
1705 S. Capital of Texas Highway
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Phone: (512) 326.9997
Fax: (512) 326.9998
Contact: Richard Vincins, Senior Consultant QA/RA

3. Date Prepared

February 20, 2009

4. Device Name

Trade/Proprietary Name: RadCalc Software
Common/Usual Name: RadCalc
Classification Name: Medical Charged Particle Radiation Therapy System – Accessory
Classification Regulation: 892.5050

5. Predicate Devices

MuCheck – Monitor Unit/Dose Program K061152
RadCalc, Model V4.0 K010464

6. Device Description

The 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.

RadCalc's function is to support the primary radiation therapy planning computer by validating its calculation as a means of quality assurance. RadCalc 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 treatment plan.

RadCalc allows for the transfer of the treatment planning data from the primary radiation therapy planning computer or the Verify and Record system to RadCalc and then to the facility's Verify and Record system or radiation therapy planning computer. This electronic transfer of treatment planning data reduces the number of errors that could occur as a result of manually inputting the data. The software does not control any radiation hardware device, but does interface with the primary radiation therapy planning software and the Verify and Record software.

7. Intended Use

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.

8. Technological Characteristics and Substantial Equivalence

The RadCalc Software is similar in design and function to the RadCalc Model v4.0 and muCheck Monitor Unit/Dose Program. These devices all have the same intended use and indications for use as the RadCalc Software. This submission is adding LDR, HDR, and Permanent Implant brachytherapy treatment plans to the indications for use. These are two recent predicate devices cleared for market by the FDA.

The RadCalc Software and the predicate devices are used on personal computers in a Windows operating system that is connected directly to the primary radiation therapy planning system. Their function is to support the primary radiation therapy planning computer by validating its calculation as a means of quality assurance. The RadCalc, Model v4.0 and 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 treatment plan.

The RadCalc Software and the predicate devices are similar in technical characteristics and performance.

9. Non-Clinical Testing

The software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans. The Device Hazard analysis was completed and risk control implemented to mitigate identified hazards. Software testing was conducted using a brachytheraphy treatment planning system and RadCalc to verify non-clinical testing. The testing results supports that the software specification are met for the acceptance of each module and interaction of processes. The RadCalc Software passed all testing and supports the claims of substantial equivalence.

10. Clinical Testing

There is no clinical testing required to support the additional indication for use of the submission. The supporting information is addressed by the non-clinical testing and beta-site testing. The verification and validation testing of the software passed all the testing and supports the claims of substantial equivalence.

11. Conclusion

The RadCalc Software has the same intended use and technological characteristics as the predicate devices.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

LifeLine Software, Inc.
% Mr. Richard Vincins
Senior Consultant QA/RA
Emergo Group
1705 S. Capital of Texas Hwy., Suite 500
AUSTIN TX 78746

Re: K090531
Trade/Device Name: RadCalc
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: February 26, 2009
Received: March 3, 2009

Dear Mr. Vincins:

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 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.

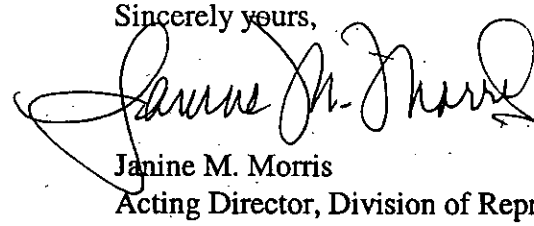
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Assigned~~ K090531

Device Name: RadCalc

Indications for Use:

RadCalc Software is a program utilized in a radiation therapy department for the determination of monitor units and/or the dose to various points of interest for external beam radiation therapy and/or brachytherapy treatments. For external beam treatments, RadCalc's monitor unit calculation can be used to validate the monitor units or dose previously determined by hand or by the primary radiation therapy planning system. RadCalc's function is to support the primary radiation therapy planning computer by validating its calculation as a means of quality assurance. RadCalc Software not only performs this secondary function but 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 treatment plan.

RadCalc Software imports treatment planning parameters from the primary treatment planning system or a verify and record system; parameters can also be entered manually. The dosimetric calculations are then performed for photon or electron external beam radiation plans or LDR, HDR, and Permanent Implant brachytherapy treatment plans. The brachytherapy treatment module is only used to validate the dose to points of interest and not for brachytherapy treatment planning.

RadCalc Software allows for the transfer of the treatment planning data from the primary radiation therapy planning computer or the Verify and Record system (system actually controlling the radiation beam) to RadCalc and then to the facility's Verify and Record system or radiation therapy planning computer. This electronic transfer of treatment planning data reduces the number of errors that could occur as a result of manually inputting the data.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090531