MAY 1 7 2001

K010464
Page 1 of 3

10. PREMARKET NOTIFICATION
Summary of Safety and Effectiveness

Submitted by:	Craig A. Laughton 403 Mockingbird Lane Tyler, Texas, 75701 (903)592-1343
Contact:	Craig A. Laughton
Date:	2/12/2001
Trade Name:	RadCalc
Common Name:	RadCalc
Classification Panel:	Radiology
Classification Name:	Medical Charged Particle Radiation Therapy System (Accessory); 21 CFR 892.5050 (class II)
Performance Standards:	none established under section 514
Substantial Equivalence:	muCheck – Monitor Unit Validation Program 510(k) K 980904 and RadCalc v1.02 (i.e. DoseCalc v1.02) – 510(k) K 990833

Description:
RadCalc is a software program that is designed to operate on a PC in a Windows environment on either a stand alone PC or on a server. It does not control any radiation hardware device but does interface with the primary radiation therapy planning software and verify and record software. The device performs monitor unit and dose calculations for photon beams which can be used to validate monitor units or dose calculated by the primary radiation therapy planning system or to simply provide the monitor units needed to treat a patient when a radiation therapy plan is not prescribed by the physician. RadCalc determines the monitor units or dose through the process looking data up from previously inputted tables or data curves.

Intended Use and Substantial Equivalence:
The intended use of RadCalc is the same as the predicate devices with a few additions that do not affect the safety and effectiveness of the device. RadCalc is a program utilized in a radiation therapy department for the determination of monitor units or dose. Radiation therapy planning 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. This is the same intended use as the predicate devices. The practice of performing a secondary check is recommended by the American Association of Physicists in Medicine (AAPM) Task Group 40 as part of good quality assurance program. This practice is an important aspect in providing quality patient care. RadCalc is not only being submitted to perform this secondary function but to 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 differs from the predicate device in this area. For this situation, it is important to accurately determine the monitor units needed for a patient's treatment. RadCalc provides this operation. It has many built in checks that will check for many common errors that occur when calculating monitor units or dose as well as checking that the inputted parameters are within predefined limits for the treatment machine. The use of RadCalc in this manner provides a means for accurately determining the monitor units. Using RadCalc in this manner is not seen as a use that effects the safety of the patient. RadCalc performs this same calculation when validating a calculation from a treatment planning system and has shown to do this very accurately (see Supporting Data). Therefore it would only seem logical to extend its use and allow for it to be used as the primary means of determining monitor units when a radiation therapy plan is not performed. A physicist can then visually examine the inputted data for accuracy and verify the computed parameters to be sure that they are correct.

RadCalc also differs from the predicate devices by allowing for the import of the treatment planning or Verify and Record data and the export of this same data to the facility's Verify and Record system or radiation therapy planning system. This will reduce the number of errors that occur as a result of manually inputting this data. This feature merely transfers information from one system to another without modifying it and is therefore not seen to be a threat to patient safety and effectiveness. In fact, it is seen to be an enhancement because it will allow for the accurate transfer of this data by eliminating the numerous human errors that occur in these processes. Data imported into RadCalc may be used to perform the monitor unit or dose computation.

Lastly, RadCalc differs from the predicate devices by allowing for the use of TLD/diode correction factors for TLD/diode based corrections.

Safety and Effectiveness:

The submitter, designer, and writer of this software, Craig A. Laughton, is a Medical Physicist certified by the American Board of Radiology and holds a Master's Degree in Medical Physics and a Master's Degree in Nuclear Engineering. He has 6 years of clinical experience and works with a PhD Physicist who has over 25 years of experience. The Intensity Modulated Radiotherapy portions of this software were developed by Craig A. Laughton in conjunction with several PhD physicists at the University of Chicago and a PhD physicist at Harvard Medical School. His, Craig A. Laughton's, experience in this field along with his conformance to the Good Manufacturing Practices Regulations has provided for the development of a product that is safe and effective for use. A User's Manual has been written for the benefit of all users of the software in order to ensure that the software is used correctly. Validation testing was performed in order to confirm that

the software performs according to the Software Requirements. These documents are included in section 9.6.

Technological Characteristics:
The technological characteristics are identical to those of the predicate devices. RadCalc was designed to be operated on a PC in the Windows environment while using the mouse and keyboard for user interaction. These are the same characteristics as the predicate devices.

Non-Clinical Tests:
The non-clinical test involved using RadCalc to perform numerous monitor unit and dose calculations under various situations. These calculations were then compared to hand calculations for the same situations or to known results for Intensity Modulated Radiotherapy based treatment plans. Side by side comparisons of these calculations are shown in the Supporting Data section just following a table summarizing the results.

Beta Testing:
Beta site testing was performed at East Texas Medical Center in Tyler, Texas and the University of Chicago Hospital in Chicago, Illinois. Numerous copies of actual calculations are presented in the Supporting Data section just following a table that summarizes the results. These calculations were either compared to a calculation performed by the primary radiation therapy planning system (ADAC's Pinnacle3 v3.0du6 or higher, K951581 for 3D based plans and NOMOS's Peacock Plan system, K940663 for Intensity Modulated Radiotherapy plans) or to a hand calculation.

Conclusions:
According to the intended use, technological characteristics, non-clinical testing, and beta site testing, RadCalc is substantially equivalent to muCheck and RadCalc v1.02 (the predicate devices). The documentation presented in this submission supports the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 7 2001

Mr. Craig A. Laughton
CEO
Lifeline Software, Inc.
403 Mockingbird Lane
TYLER TEXAS 75701

Re: K010464
RadCalc V4.0
Dated: February 13, 2001
Received: February 16, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Mr. Laughton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010464

Device Name: RadCalc v4.0

Indications For Use:

RadCalc is a program utilized in a radiation therapy department for the determination of monitor units and the dose at point of calculation. RadCalc's monitor unit calculation can then be used to validate the monitor units or dose previously determined by hand or by the primary radiation therapy planning system. 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. RadCalc is not only being submitted to perform this secondary function but to 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 also 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010464