JUN 8 1999

K990833

10. PREMARKET NOTIFICATION
Summary of Safety and Effectiveness

Submitted by: Craig A. Laughton
403 Mockingbird Lane
Tyler, Texas, 75701
(903)595-0209

Contact: Craig A. Laughton

Date: 3/08/99

Trade Name: DoseCalc

Common Name: DoseCalc

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

Description:
DoseCalc 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 calculations for photon beams which can be used to validate monitor units 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. DoseCalc determines the monitor units through the process looking data up from previously inputted tables.

Intended Use:
The intended use of DoseCalc is the same as the predicate device with a few additions that do not affect the safety and effectiveness of the device. DoseCalc is a program utilized in a radiation therapy department for the determination of monitor units. 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, DoseCalc will serve to validate those monitor units computed by the primary

radiation therapy planning system. This is the same intended use as the predicate device. 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. DoseCalc 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. DoseCalc 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. DoseCalc provides this operation. It has many built in checks that will check for many common errors that occur when calculating monitor units as well as checking that the inputted parameters are within predefined limits for the treatment machine. The use of DoseCalc in this manner provides a means for accurately determining the monitor units. Using DoseCalc in this manner is not seen as a use that effects the safety of the patient. DoseCalc 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.

DoseCalc also differs from the predicate device by allowing for the import of the treatment planning data and the export of this same data to the facility's Verify and Record 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 performing any calculations 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.

Safety and Effectiveness:

The submitter, designer, and writer of this software, Craig A. Laughton, is a Medical Physicist with a Master's Degree in Medical Physics and a Master's Degree in Nuclear Engineering. He has 4 years of clinical experience and works with a PhD Physicist who has over 25 years of experience. 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 device. DoseCalc 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 device.

Non-Clinical Tests:
The non-clinical test involved using DoseCalc to perform numerous monitor unit calculations under various situations. These calculations were then compared to hand calculations for the same situations. 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. 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 APEX, K951581) or to a hand calculation.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 1999

Craig A. Laughton
President
Integrity Medical Software, Inc.
403 Mockingbird Lane
Tyler, Texas 75701

RE: K990833
DoseCalc v1.02 Medical Charged Particle Radiation Therapy System
Dated: March 9, 1999
Received: March 12, 1999
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) 594-4613. 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"(21 CFR 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990833

Device Name: DoseCalc v1.02

Indications For Use:

DoseCalc is a program utilized in a radiation therapy department for the determination of monitor units. The Monitor Unit is a quantity used by a treatment machine for determining the length of time that it should remain on in order to deliver a prescribed amount of radiation to a point. Most of the time, a radiation treatment planning system is used to define the location and dose distribution of the radiation. Radiation therapy planning systems typically calculate the monitor units needed to deliver the desired amount of radiation to a point of reference and thus produce the desired dose distribution within the patient. On occasion, a hand calculation will be performed in order to determine the number of monitor units needed to deliver the prescribed amount of radiation. DoseCalc is a program which allows the user to input data by hand through the use of the mouse or keyboard or electronically from the primary radiation therapy planning system. From this data, it will then determine the number of monitor units needed to be given to a patient. The process of calculating the monitor units involves DoseCalc automatically looking up the data parameters from previously inputted data and then calculating the monitor units from these values. This process greatly increases the speed at which a calculation can be performed and also eliminates many errors that occur from manually looking up the data. DoseCalc's monitor unit calculation can then be used to validate the monitor units previously determined by hand or by the primary radiation therapy planning system. It is not the intention of DoseCalc 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 good quality assurance program. This practice is an important aspect in providing quality patient care. DoseCalc 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. For this situation, it is important to accurately determine the monitor units needed for a patient's treatment. DoseCalc provides this operation. It has many built in checks that will check for many common errors that occur when calculating monitor units as well as checking that the inputted parameters are within predefined limits for the treatment machine. The use of DoseCalc in this manner provides a means for accurately determining the monitor units. A physicist can then visually examine the inputted data for accuracy and verify the computed parameters to be sure that they are correct.

DoseCalc also allows for the transfer of the treatment planning data from the primary radiation therapy planning computer to DoseCalc and then to the facility's Verify and Record 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 performing any calculations.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Williams for Daniel Schultz, M.D.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990833

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)