FEB 1 0 2000

K992689
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510(k) Summary

Submitter:	Rad Therapy Solutions, Inc. 738 Alden Drive Ormond Beach, FL 32176 Tel. (904) 441-7400 Email: muplus1@aol.com
Contact:	Steve Gruse, President
Date:	August 7, 1999
Trade Name:	MU Plus!
Common Name:	Monitor Unit Calculation Verification Program
Classification Panel:	Radiology
Classification Name:	Medical Charged Particle Radiation Therapy System (Accessory) 21 CFR 892.5050 (class II)
Substantial Equivalence:	K&S Associates, PC Setup Program 510(k) K914698 SSGI, Prowess Pro-Sim 510(k) K980379

Description:

The MU Plus! monitor unit calculation verification program is designed to operate on an IBM compatible personal computer using Windows 95, Windows NT 4.0, or higher operating system. It is designed to operate independently of any radiation treatment planning system. It does not connect to or control any radiation hardware device. It is designed to verify monitor unit calculations for accelerator produced photons and electrons. It also calculates expected diode readings based on clinical data entered by the user.

Intended Use:

The intended use of the MU Plus! monitor unit calculation verification program is the same as for the predicate devices: to calculate monitor unit or timer settings for the purpose of validating a monitor unit or timer setting previously calculated by a radiation treatment planning system or hand calculation. MU Plus! also calculates an expected diode reading which is used to verify proper delivery of radiation therapy treatment.

Technological Characteristics:

MU Plus! calculates monitor unit settings in a fashion similar to Prowess for photon calculations. MU Plus! calculates monitor unit settings for photons using the following formalism:

$$MU = \frac{\text{Calculated Dose}}{\text{TMR} * \text{Sp} * \text{Sc} * \text{WF} * \text{TF} * \text{OAFx} * \text{OAFy} * \text{ISF} * \text{Output (cGy/MU)}}.$$

Prowess calculates monitor settings for photons using the following formalism:

$$MU = \frac{\text{Calculated Dose}}{\text{TMR} * \text{OF} * (\text{PSF'}/\text{PSF}) * \text{WF} * \text{TF} * \text{ISF} * \text{Output (cGy/MU)}}.$$

where: $\text{OF} * (\text{PSF'}/\text{PSF}) = \text{Sp} * \text{Sc}$

MU Plus! calculates monitor unit settings in a fashion similar to PC Setup Program for electrons. MU Plus! calculates monitor unit settings for photons using the following formalisms:

$$MU = \frac{\text{Calculated Dose}}{\text{Cone Output Factor} * \text{SSD Output Factor} * \text{Isodose Prescription}}.$$

OR

$$MU = \frac{\text{Calculated Dose}}{\text{Calibration Factor} * \text{Isodose Prescription}}.$$

PC Setup Program calculates monitor unit settings for electrons using the following formalism:

$$MU = \frac{\text{Calculated Dose}}{\text{Cone Output Factor} * \text{Modifier Factor} * \text{Isodose Prescription}}.$$

Although terms in these formalism may differ slightly, the formalism is essentially the same for both MU Plus! and PC Setup Program.

Non-clinical tests:

Non-clinical tests were conducted using the predicate devices and MU Plus!. Standard test cases were used on both systems. The test results matched very closely which supports the claim of substantial equivalence. See Appendixes A and B for a comparison summary.

In addition monitor unit settings calculated by MU Plus! were compared against those performed by manual lookup to verify that the program was performing monitor unit calculations correctly. All tests matched very closely. See Appendixes C and D for a comparison summary.

Conclusions:

Based on the technological characteristics, intended use, non-clinical tests, as well as clinical tests, MU Plus! is substantially equivalent to the predicate device. The documentation submitted for review supports this claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2000

Steve Gruse, M.S., DABR
President
Rad Therapy Solutions, Inc.
738 Alden Drive
Ormond Beach, Florida 32176

Re: K992689
MU Plus !
Dated: November 12, 1999
Received: November 18, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Gruse:

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

Statement of Indications of Use

Applicant: Rad Therapy Solutions, Inc.

510(k) Number: N/A K992689

Device Name: MU Plus!

Indications For Use:

MU Plus! is a quality assurance tool for monitor unit calculations performed in radiation oncology clinics. MU Plus! is designed to be used as a verification of treatment planning derived monitor unit settings or hand generated monitor unit settings. Monitor unit calculations for linear accelerators are performed by various staff of radiation oncology clinics, including medical physicists, dosimetrists, and radiation therapists. MU Plus! also contains a diode measurement verification program which predicts an expected diode reading based on a formalism similar to the monitor unit calculations.

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992689/S001