

K101503

File: dcexit510ksummary.doc

Date: 29 April 2010

5. 510(k) Summary

AUG 04 2010

Dosimetry Check with Exit Dose is a software program intended to provide a means for testing the dosimetry of radiation therapy treatments applied to a patient using high energy x-rays. This test is performed from measurements made during treatment of the patient by measuring the radiation fields after they have passed through the patient with a suitable imaging device such as an electronic portal imaging device or other measuring devices or media. The following software functions are then performed:

1. The patient's CT scan treatment plan image set is traced to provide the water equivalent path to points on the measured exit dose plane.
2. A deconvolution process is performed with a kernel that is a function of radius and the thickness transversed to convert the exit images back to x-ray intensity in air fluence prior to patient entry. The kernel is derived prior from phantom measurements with the same imaging device or media.
3. The derived in air fluence is now the same starting point as when the radiation fields are measured directly prior to patient entry.
4. The existing Dosimetry Check (FDA 510(k) K010225) software functions are then used to compute the dose to the patient using the in air fluence for each treatment beam and to evaluate the correctness of the dose to the patient.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Wendel Dean Renner
President
Math Resolutions, LLC
5975 Gales Lane
COLUMBIA MD 21045

AUG 04 2010

Re: K101503

Trade/Device Name: Dosimetry Check with Exit Dose
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 27, 2010
Received: June 1, 2010

Dear Mr. Renner:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

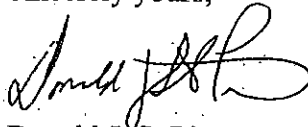
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

File: dcexitinduse.doc

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4. Indications for Use

510(k) Number K101503

AUG 04 2010

Device Name: Dosimetry Check with Exit Dose

Indications for Use:

The product is to be used by radiation oncologist, dosimetrist, and radiation therapy physicist to check the correctness of the x-ray treatment fields from high energy treatment machines that are planned to be or have been applied to a patient. This product is to be used in addition to the treatment planning system to provide a means for additional and redundant verification that the plan is in fact successfully accomplished. This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the measurement of each x-ray field and a theoretical calculation. This product does not provide any quality assurance that the fields are in fact correctly applied to and correctly aligned with the patient anatomy as planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.

Document approved by: Wendel Dean Renner

Title: President

Date: 29 April 2010

Wendel Dean Renner

Michael D. Starna

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K

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