Title:	Document ID:	Version:
510(k) Application - RayDose	RSL-D-54-30	1.0

5. 510(k) Summary RayDose

5.1 510(k) owner

RaySearch Laboratories AB
Sveavägen 25, plan 9
111 34 Stockholm
Sweden

Tel: +46 (8) 54506130
Fax: +46 (8) 54506139

OCT 2 2 2008

5.2 Contact person

Anders Murman

5.3 Preparation date

03/29/2007

5.4 Trade name

RayDose

5.5 Common name

Radiation therapy dose calculation engine

5.6 Classification name

Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code MUJ)

5.7 Predicate devices

DCM 1.0	510(k) number K011246
Pinnacle^3 Radiation Therapy Planning System	510(k) number K041577

5.8 Device description

RayDose is a software program, which offers dose calculation, either as a separate unit or as a service to other software programs.

In short, RayDose needs the following input:

- A patient or phantom description, normally CT images and regions-of-interest
- A treatment plan
- Settings needed for the dose calculation (such as dose grid and algorithm)

RayDose computes dose to all points in the chosen dose grid, by means of applying the beams of the treatment plan onto the patient or phantom geometry. This dose computation uses the following algorithms:

- For fluence, a first principle physics based three-source fluence algorithm exists, where the first source models the collimated primary fluence, the second source models scattered and transmitted fluence from all parts of the treatment head and the third source models electron contributions to the photon fluence.
- A collapsed cone algorithm (CC) for calculating bulk doses given impinging fluence exists. This algorithm has a high accuracy also for inhomogeneities in the patient or phantom geometry.

As output, RayDose produces dose values in the chosen dose grid.

The software runs on a Windows XP platform.

5.9 Intended use

RayDose is software that computes dose (energy per volume deposited by ionizing radiation) three-dimensionally in a geometrical representation of a patient or a phantom, stemming from an external beam treatment unit in a radiation oncology clinic. The computed dose is intended to be used for clinical decisions on planned treatments or in quality assurance contexts.

Based on various input data, RayDose is used to compute dose for linear accelerators with X-ray energies from 6 to 18 MV, supporting the following collimation and modulation modalities:

- Symmetric and asymmetric rectangular fields
- Multileaf collimated fields
- Coplanar and non-coplanar fields
- Intensity modulated fields using Step-and-shoot technique
- Intensity modulated fields using Sliding Window technique

5.10 Technological characteristics summary

The technological characteristics are the same for RayDose as for DCM 1.0 and Pinnacle^3 Radiation Therapy Planning System. All three devices compute fluence for external photon beams using a physics-based algorithm modeling both the primary and scatter fluence and electron contributions. All three devices compute dose in three dimensions from the fluence using a collapsed cone algorithm.

DCM 1.0 and RayDose support symmetric and asymmetric fields, multileaf collimators, coplanar and non-coplanar fields and intensity modulated step-and-shoot fields.

Pinnacle^3 Radiation Therapy Planning System and RayDose support intensity modulated sliding window fields, also known as dynamic multileaf collimated fields.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2008

RaySearch Laboratories AB
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K082221
Trade/Device Name: RayDose
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: MUJ
Dated: October 3, 2008
Received: October 7, 2008

Dear Mr. Lehtonen:

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 either class II (Special Controls) or class III (PMA), 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 898. 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 Part 801); 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.

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 Part 801), please contact the 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 894.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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): - K082221

Device Name: RayDose 1.0

Indications For Use:

RayDose is software that computes dose (energy per volume deposited by ionizing radiation) three-dimensionally in a geometrical representation of a patient or a phantom, stemming from an external beam treatment unit in a radiation oncology clinic. The computed dose is intended to be used for clinical decisions on planned treatments or in quality assurance contexts.

Based on various input data, RayDose is used to compute dose for linear accelerators with X-ray energies from 6 to 18 MV, supporting the following collimation and modulation modalities:

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- Intensity modulated fields using Step-and-shoot technique
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Prescription Use YES (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use NO (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 K082221