5. 510(k) Summary RayAutoplan

K083264

JAN 22 2009

5 1 510(k) owner

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Sweden

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5 2 Contact person

Anders Murman

5 3 Preparation date

09/01/2008

5 4 Trade name

RayAutoplan, alias **t-RayAutoplan**, alias **SharePlan**

RayAutoPlan is the product name RaySearch will use moving this device into the world market

t-RayAutoplan was the name of the product during the development project, and when seen in the documentation related to this application, it is the same as RayAutoplan, by definition

SharePlan is the trade name TomoTherapy Inc will use on the world market, as being the exclusive distributor of this device This name is not further used in the documentation of this application

5 5 Common name

Radiation treatment planning system

5 6 Classification name

Medical charged-particle radiation therapy system (21 CFR 892 5050, Product Code MUJ)

5 7 Predicate devices

Oncentra MasterPlan v3 1 510(k) number K081281

5 8 Device description

RayAutoplan is a stand-alone software program that generates a number of treatment plans, based on the dose distribution exported from a TomoTherapy treatment planning system

Detailed information of RayAutoplan can be found in reference 1, Customer requirement specifications

However, the most important workflow is described below

Flow of Events

	User	*System*
1	The user launches RayAutoplan	
2	The user selects the transferred TomoTherapy case from a list of TomoTherapy cases	
3		The system imports the data and checks consistency of in-data
4	The user selects machine and treatment energy	
5	The user selects MLC delivery mode (SMLC/DMLC)	
6	The user specifies beam configuration	
7	The user specifies which plan family or families that should be generated	

8 The user starts the automatic plan generation	
	9 The system generates plans 10 The system displays plans as - 2D and 3D dose and patient displays - Dose difference maps - DVHs (several overlaid in same graph) - Dose statistics - Plan data (machine, beams, segments and so on)
11 The user reviews the Linac plans	
12 The user selects a plan for approval and generates plan documentation	
	13 The system creates a report containing - Patient info - Plan info - Dose info
14 The user approves the plan for delivery	
	15 Prints plan documentation and exports plan to DICOM archive or R&V system

Alternative workflows exist, including automatic plan generation and beam commissioning

To execute, RayAutoplan needs the following input

- A patient description, normally CT images and regions of interests
- A dose distribution serving as a reference dose, which should be benchmarked

As output, RayAutoplan produces a linac IMRT treatment plan and the corresponding dose distribution from an accurate calculation of the dose engine

The software runs on a Windows XP or Windows Vista platform

5 9 Intended use

RayAutoplan is a software that, based on the planned dose distribution from a TomoPlan treatment planning system, generates a family of individually optimized IMRT plans and presents their characteristics to the user in a GUI Among the generated plans, the user selects and clinically approves a treatment plan and exports it electronically to DICOM, for subsequent treatment of the patient

The intended users of RayAutoplan shall be clinically qualified staff, such as medical physicists, medical doctors or dosimetrists

5 10 Technological characteristics summary

The technological characteristics are the same for RayAutoplan as for Oncentra MasterPlan v3 1 Both devices produce IMRT treatment plans with corresponding dose distributions computed using a three dimensional collapsed cone dose engine Both devices have a function of electronic clinical approval of treatment plans by trained and authorized staff, and finally export in DICOM format for commencing treatment or archiving

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

RaySearch Laboratories AB
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Re K083264
Trade/Device Name RayAutoplan 1 0
Regulation Number 21 CFR 892 5050
Regulation Name Medical charged-particle radiation therapy system
Regulatory Class II
Product Code: MUJ
Dated January 5, 2008
Received January 6, 2008

Dear Mr Kogoma

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 os 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 892 xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Manufactures, 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 suppot/index html

Sincerely yours,

Janine M Morris
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) - K083264

Device Name RayAutoplan 1 0

Indications For Use

RayAutoplan is a software that, based on the planned dose distribution from a TomoPlan treatment planning system, generates a family of individually optimized IMRT plans and presents their characteristics to the user in a GUI Among the generated plans, the user selects and clinically approves a treatment plan and exports it electronically to DICOM, for subsequent treatment of the patient

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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 K083264