C-RAD

K082582

MAR 3 0 2009

510(k) SUMMARY

Owner

C-RAD Positioning AB
Bredgränd 14
753 20 Uppsala
Phone no: +46 18 666930
Fax no: +46 18 126930

Contact person

Cristina Svensson
Chief Executive Officer
Phone no: +46 18 666936

Date of preparation

September 1, 2008

Trade name of device

Sentinel

Common name

Radiotherapy positioning system

Classification name

Medical charged-particle radiation therapy system
Regulation: 21 CFR 892.5050

Predicate marketed devices

AlignRT (K052682) – Vision RT Ltd.

Device description

The Sentinel system is a new version of the Positioner system (previously registered with 510(k) Number K063839), updated with an application module for patient monitoring, cMotion (the design control documents are included in Appendices A and B).

Sentinel is an advanced system for surface contour localization and patient monitoring during the radiotherapy treatment process. The Sentinel platform is based on advanced laser technology with multipurpose software modules covering different tasks in the treatment procedure. The c4D multi-application software supports all modes of operation in one integrated package. The software is user friendly and requires a minimum of user interaction in the daily clinical workflow, while providing the advanced user with sophisticated data management, analysis and reporting functionalities. The software is designed to integrate with existing systems at the clinic, such as CT, linacs and R&V systems, and with motorized couch tops.

Sentinel includes two application modules, cPosition for fast and accuracy patient positioning and cMotion for motion detection during the treatment delivery procedure.

The Sentinel hardware consists of a single scanner unit containing the laser and camera, mounted in the ceiling in front of the gantry. The scanner is connected to the PC running the c4D software.

During patient surface acquisition, a laser line is swept along the patient while the camera records a number of images. From the data acquired, a complete 3D surface of the patient can be reconstructed using laser line triangulation. For patient positioning, the acquired surface is captured in a few seconds and can contain several hundred contours. For motion detection the number of contours is typically lowered so that the desired frame rate is achieved.

cPosition

Once the treatment planning has been performed, the resulting plan can be transferred to the Sentinel system through import from the industry-standard DICOM format, creating the reference data necessary for patient positioning. Reference data can also be by created using the Sentinel laser scanner. In the treatment room, synchronization with the LINAC or R & V (Record and Verify) system ensures that the correct reference data is called up automatically when the patient is selected for treatment, and also eliminates the need for any manual selection of the patient in the Sentinel system.

By advanced surface registration algorithms the actual patient position is compared to the predefined reference, suggesting within seconds a correction in six degrees of freedom of the patient's position. With interface to major accelerator vendors the suggested patient position is transferred to the respective couch control system and fast and accurate alignment is achieved.

cMotion

cMotion monitors the movement of the patient during treatment delivery and automatically warns if the patient moves outside the allowed tolerances.

Intended use

The Sentinel system is intended for use in radiation therapy clinics to accurately position patients in a reproducible way, prior to treatment and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment.

Technological comparison

The Sentinel system is substantial equivalent to the predicate devices in terms of their intended use and technological characteristics. There are differences between the Sentinel system and predicate devices in terms of their principles of operation, materials, performance, human factors and energy delivered by the system. However, performance data has been submitted to show that Sentinel achieves its intended use and that these technological differences raise no new efficacy or safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2009

Ms. Cristina Svensson
CEO
C-RAD Positioning AB
Bredgränd 14
Uppsala 75320
SWEDEN

Re: K082582
Trade/Device Name: Sentinal
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 23, 2009
Received: February 26, 2009

Dear Ms. Svensson:

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

INDICATIONS FOR USE

510(k) Number: K082582

Device Name: Sentinel

Indications for use:

The Sentinel system is intended for use in radiation therapy clinics to accurately position patients in a reproducible way, prior to treatment and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082582

Prescription Use ✓