K102024

Premarket Notification [510(k)] Summary
RPM Respiratory Gating System

OCT 15 2010

The following information is provided following the format of 21 CFR 807.92.

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way e-110 Palo Alto, CA 94304 Contact Name: Vy Tran Phone: 650/424.5731 Fax: 650/842.5040 Date: 14 July 2010
Proprietary Name:	RPM Respiratory Gating System
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050, Class II Product Code: IYE, LHN
Common/Usual Name:	RPM Respiratory Gating System
Predicate Devices:	RPM Respiratory Gating System (K063270)
Device Description:	The Varian RPM Respiratory Gating is an attachment to radiation therapy treatment systems such as conventional linear accelerators, proton therapy systems, radiation therapy simulators and image acquisition devices used for diagnostics and radiation therapy. The RPM device is to be used to characterize the patient's respiratory motion information to synchronize their operation with the respiratory motion. The imaging devices either trigger the image acquisition based on the signal received from RPM, or they use respiratory motion signal to trigger beam-hold and limit the beam-on time to those points in the respiratory cycle where the target volume is within acceptable motion limits. The RPM device can also be used to monitor the patient's position during the image acquisition and treatment therapy process.
Statement of Intended Use	The RPM Respiratory Gating System is used to obtain tracking of the subject respiratory pattern for respiratory synchronized image acquisition and radiation therapy treatment. It can also be used to monitor the patient position during image acquisition, simulation and treatment.
Statement of Indications for Use:	The RPM Respiratory Gating System is used to obtain tracking of the subject respiratory pattern for respiratory synchronized image acquisition and radiation therapy treatment. It can also be used to

monitor the patient position during image acquisition, simulation and treatment.

Technological Characteristics: See device comparison table below.

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION	DEVICE WITH CHANGE
Intended Use	The RPM Respiratory Gating System is used to obtain tracking of the subject respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. It can be also used to monitor the patient position during the image acquisition, simulation and treatment.	No change
Indications for Use	The RPM Respiratory Gating System is used to obtain tracking of the subject respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. It can be also used to monitor the patient position during the image acquisition, simulation and treatment.	No change
Objects physically attached to patient	Light plastic block with retro-reflective markers (2 or 6 dots), positioned typically on patient's upper abdomen or chest area.	No change
Wire connections made to patient	None	No change
Measured parameters	Vertical, lateral and longitudinal position of the marker block, which is typically positioned on patient's abdomen or chest in video camera field of view.	No change
Maximum signal range	32 cm vertical by 41 cm lateral at 380 cm working distance from video camera with 50 mm lens; 29 cm vertical by 38 cm lateral at 180 cm working distance from the camera with 25 mm lens.	No change
Measurement resolution	At 380 cm distance from the camera using 50 mm lens (cm): Vertical: 0.013 Lateral: 0.023 Longitudinal: 0.055 At 180 cm distance from the camera using 25 mm lens (cm): Vertical: 0.004 Lateral: 0.002 Longitudinal: 0.018	No change
Measurement drift	None	No change
Distance to patient	15 ft maximum patient-camera distance	No change
Compatible with radiation therapy treatment devices	Yes (Varian accelerators)	Varian Linear Accelerators, Proton therapy Systems that are capable of being gated.
Compatible with radiation therapy simulators	Yes	No change

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION	DEVICE WITH CHANGE
Compatible with image acquisition systems used in radiation oncology and diagnostics.	Yes (General interface) Support for both triggered/gated and 4D image acquisition.	No change
Supported patient coaching methods	Audio and/or visual	No change
Supported breathing methods	Free-breathing, voluntary breath-hold	No change
Patient position monitoring	Yes	No change
Recognition and management of periodicity changes in respiratory pattern	Yes	No change
Support for phase based and amplitude based gating	Both phase and amplitude based gating	No change

Summary of Performance Testing

Results of verification and validation testing demonstrate that the RPM Respiratory Gating System satisfies the intended use as described above.

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

Ms. Vy Tran
Vice President
Varian Medical Systems
3100 Hansen Way
PALO ALTO CA 94304

OCT 15 2010

Re: K102024
Trade/Device Name: RPM Respiratory Gating System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 14, 2010
Received: July 19, 2010

Dear Ms. Tran:

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,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

OCT 15 2010

Indications for Use

510(k) Number (if known): K102024

Device Name: **RPM Respiratory Gating System**

Indications for Use:

The RPM Respiratory Gating System is used to obtain tracking of the subject respiratory pattern for respiratory synchronized image acquisition and radiation therapy treatment. It can also be used to monitor the patient position during image acquisition, simulation and treatment.

Prescription Use _____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102024