K063270

VARIAN
medical systems

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510(k) Summary

DEC 14 2006

The following information is provided following the format of 21 CFR §807.92 for the RPM Respiratory Gating System.

1. **Submitter:**
Varian Medical Systems
3100 Hansen Way M/S E-110
Palo Alto, CA 94304-1129
Contact Name: Vy Tran
Phone: (650) 424-5731
Fax: (650) 842-5040
Email: vy.tran@varian.com
Date summary was prepared: October 25th, 2006

2. **Name of the Device:** **RPM Respiratory Gating System**
Trade/Proprietary Name: RPM Respiratory Gating System
Common or Usual Name: Respiratory Gating System
Classification Name: Medical Charged-particle radiation therapy system.
21 CFR §892.5050
Class II
Product Code: IYE

3. **Predicate Device:** RPM Respiratory Gating K983629

4. **Description of the Device:** The Varian RPM Respiratory Gating Device is an attachment to the Varian Clinac radiation therapy treatment systems, radiation therapy simulators, and image acquisition devices used for diagnostics and radiation therapy. The RPM system senses and records the respiratory motion and respiratory state of a patient using video tracking of an optical marker placed on the patient to a location indicated by the physician. Video camera is connected to a PC workstation is used for video tracking of markers.

5. **Intended Use Statement:** 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.

6. **Summary of the Technological Characteristics:** The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. The comparison chart demonstrates that the device is substantially equivalent to its predicate device cited in the table. This chart is located in Tab 7 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC 14 2006

Ms. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K063270
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: October 26, 2006
Received: October 30, 2006

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 either class II (Special Controls) or class III (Premarket Approval), 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). 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,

Nancy C Brogdon

Nancy C. Brogdon
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 (if known): K063270

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 be also used to monitor the patient position during the image acquisition, simulation and treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063270