

JUN 8 1999

**Premarket Notification [510K] Summary
as required by 21 CFR 807.92**

K983629

Date Summary was prepared:

October 13, 1998

Submitter's Name:

Varian Oncology Systems
3045 Hanover Street
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Contact Person:

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Safety Manager
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Device Name:

RPM Respiratory Gating System

Classification Name:

Radiographic ECG/Respirator Synchronizer, 90IXO

Predicate Device:

NIMS Respitrace System, K864886

Product Description:

The video-based RPM Respiratory Gating System provides a respiration gating signal to a Clinac radiation therapy machine to "hold" the beam during planned intervals of the respiration cycle. The system derives beam-hold signals from the patient chest motion, which it tracks using a video camera connected to a PC workstation. The computer includes real-time and multi-channel video digitization and display hardware controlled by digital image analysis and video tracking software that runs as a Windows NT application. The PC also includes a relay and I/O board that under software control opens and closes the Clinac gating switch for beam-hold control.

The RPM Respiratory Gating System receives live video images from a monochrome CCD video camera equipped with an infrared ring illuminator. When used for planning, the RPM Respiratory Gating System receives images from both the camera and a simulator or fluoroscope. For treatment use, the RPM Respiratory Gating System receives images from the camera.

Before the operator can work with the system, the operator must create or select patient and session data records from a patient information database. The operator then records new data or displays recorded data for the current patient and session.

When the system is used for planning, the treatment is simulated. The operator sees live fluoroscopic images of the simulated treatment field, which are used to set the gating thresholds applied to the motion plots simultaneously generated by tracking the respiration motion. When used for treatment, the radiation beam is actively gated by the system, so that the beam is held (not irradiating) when the motion is outside the thresholds set in the planning session.

Intended Use:

To obtain tracking of the subject respiratory pattern for radiation therapy treatment.

Technological Characteristics:

See the attached "Comparison of Characteristics and Specifications Table".

Table 2 shows substantial functional equivalence of RPM Respiratory Gating System and Resptrace technologies as respiratory monitoring devices. Only the specifications that are relevant to the goal of RPM Respiratory Gating System are compared in the table.

Table 2 – Comparison of characteristics and specifications of RPM Respiratory Gating System and Resptrace

Characteristic/Specification	RPM Respiratory Gating System	Resptrace	Comments
Objects physically attached to patient	Light foam block with retro-reflective marker on it attached to upper abdomen area	Respiband inductive coil ribbon wrapped around the patient stomach or rib cage	
Wire connections made to patient	None	Wires connecting Respiband to the computer and control box	
Measured parameter	Vertical position of the marker attached to abdomen in video camera field of view	Resptrace output voltage is a measure of inductance of Respiband coil wrapped around the abdomen or rib cage. Inductance varies with the length of the coil, which in turn varies, with circumference of the band wrapped around the body.	RPM Respiratory Gating System responds to the motion of the whole body as well as respiratory motion, while Resptrace responds to motion only due to abdomen or rib cage size change.
Maximum signal range	0 to 479 (row position in vertical field of view of video image) for NTSC video camera.	-5V to +5V	RPM Respiratory Gating System vertical camera field of view varies as a function of camera-marker block distance. For the RPM Respiratory Gating System optics the vertical FOV as a function of distance is: $V\text{-FOV} = 0.12 * \text{Distance}$.

			For example at 250-cm distance the V-FOV is 30 cm.
Measurement resolution	0.1 pixels standard deviation	1 mV	The RPM Respiratory Gating System resolution is equivalent to 1 / 4800 of V-FOV. This translates to $0.1 * 30 / 480 = 0.00625$ cm, or 0.0625 mm at 250 cm distance.
Measurement drift	None	10 mV per second	
Sampling rate	30 Hz	200 samples/sec for A/D converter. The Resptrace output signal bandwidth is 25 Hz.	
Distance to patient	15 Ft Maximum patient-camera distance	10 Ft Resptrace cable length	



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Linda Nash
Regulatory Affairs & Quality Assurance Manager
Varian Oncology Systems
3045 Hanover Street
M/S H055
Palo Alto, California 94304-1129

Re: K983629
RPM Respiratory Gating System
Dated: March 8, 1999
Received: March 10, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 LNH
Regulatory Class: I
21 CFR 892.1970/Procode: 90 IXO

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Varian Oncology System

Indications For Use

510(k) Number (if known): K983629

Device Name: RPM Respiratory Gating

Indications for Use:

The Varian RPM Respiratory Gating device is an attachment to the radiation therapy simulator and Varian Clinac radiation therapy treatment system. It is to be used to characterize (in simulation) the patient's respiratory patterns and then, in treatment, 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (per 21 CFR 801.109)

OR

Over-The-Counter Use



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K983629