

AUG 15 1997

K971839



**SUMMARY OF
SAFETY AND EFFECTIVENESS
INFORMATION**

1. Submitter: Varian Oncology Systems
3045 Hanover Street
Palo Alto, CA 94304

Contact: Charles H. Will, Manager
Regulatory Compliance &
Safety
Phone: (415) 424-5036
FAX: (415) 424-4830

Prepared: May 15, 1997

2. Device Name: Radiation Therapy Imaging System (RTIS)

3. Predicate Device: Electronic Portal Imaging System
510(k) 901932B
Cleared on May 3, 1991

4. Description: RTIS is a component of imaging systems for use with radiotherapy devices such as linear accelerators and simulators for various imaging tasks. It may be integrated into systems such as Varian PortalVision® and VARiS® Digital Imaging Option and offers the capability of a realtime imager that can provide both high quality simulator fluoroscopic/radiographic images and high energy treatment images.

5. Intended Use: Allows the therapist to have the capability of a realtime imager that can provide either high quality simulator fluoroscopic/radiographic images or high energy treatment images.
6. Technological Considerations: Whereas the imaging mechanism in the predicate Electronic Portal Imaging System is an ionization chamber, for RTIS it is an image detector. The image detector is a photo-diode array of thin film transistors (TFT) based on amorphous silicon technology. When used in combination with a scintillating material, the array can be used for x-ray imaging applications. The array contains 512 x 512 pixels which convert light into electrical charge. Each of the pixels contain a TFT which transfers the charge to the data lines when a voltage pulse is applied to the gate line. The charge is read from the data by external amplifiers.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Charles H. Will
Manager, Regulatory Compliance & Safety
Varian Associates, Inc.
3045 Hanover Street
Palo Alto, California 94304-1129

Re: K971839
Varian Radiation Therapy Image Acquisition System
Dated: May 15, 1997
Received: May 19, 1997
Regulatory class: II
21 CFR 892.5840/Procode: 90 KPQ

Dear Mr. Will:

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 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 requirement, 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/dsmamain.html>

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971839

Device Name: Varian Radiation Therapy Imaging System (RTIS)

Indications For Use: RTIS is an imaging accessory indicated for use with radiotherapy devices such as linear accelerators and simulators. It provides radiographic/fluoroscopic images for simulations, and portal images for high energy treatment machines.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971839

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter Use _____