FEB 27 2004

K040192

510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the On-Board Imager Device.

1. **Submitter:** Varian Medical Systems
   3100 Hansen Way M/S H055
   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: January 27, 2004

2. **Name of the Device:** **On-Board Imager**
   Trade/Proprietary Name: On-Board Imager Device
   Common or Usual Name: Imaging Accessory to Medical Linear Accelerator
   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code: 90 IYE

3. Predicate Devices to claim substantial equivalence:
   a. Varian Medical Systems'PortalVision, K003636
   b. Elekta Synergy, K032996

4. Description of the Device: PortalVision has been modified to add a kilovoltage x-ray source and digital imaging system to allow for improved image quality. This additional option will be called the On-Board Imager device and its intended use will be to supplement the PortalVision device or be used as a stand-alone device to allow for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation anatomical and/or fiducial landmarks.

5. Intended Use Statement: The On-Board Imager device is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.

6. Summary of the Technological Characteristics: The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. This chart is located in Tab 8 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

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

Re: K040192
Trade/Device Name: On-Board Imager
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: January 27, 2004
Received: January 28, 2004

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 (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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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): K040192

Device Name: On-Board Imager

Indications for Use:

The On-Board Imager device is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

AND/OR

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040192