OCT 2 9 2004

K042720

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 E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
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Fax: (650) 842-5040
Email: vy.tran@varian.com
Date summary was prepared: September 30, 2004

2. **Name of the Device:**

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'On Board Imager, K040192

4. **Device Description:** The On-Board Imager device has been modified to include the already cleared CBCT (cone-beam CT) option for the Acuity simulator (K033339) so that cone-beam CT image acquisition will be available in the treatment room. This will allow users to acquire cone-beam CT images of the patient while they are on the treatment couch in the treatment room. The users can then compare the locations of soft-tissue anatomy seen in reference CT scans with the locations of the same soft-tissue anatomy in the cone-beam CT images. The reference CT images can come from multiple sources including conventional CT scanners, the Acuity simulator or previous cone-beam CT scans acquired using the On-Board Imager.

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

OCT 2 9 2004

Ms. Vy Tran
Corporate Director, Regulatory Affairs
VARIAN Medical Systems, Inc.
3100 Hansen Way M/S E-110
PALO ALTO CA 94304-1038

Re: K042720
Trade/Device Name: On-Board Imaging Device
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: September 30, 2004
Received: October 1, 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 (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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (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

510(k) Number (if known): K042720
Device Name: On-Board Imager Device

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use √

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042720