K091209

510(k) Summary

The information below is provided for the Modifications to Portal Vision™ known as PortalVision Advanced Imaging, following the format of 21 CFR 807.92.

1. Submitter:

Varian Medical Systems
3100 Hansen Way, M/S e110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: 650/424.5731
Fax: 650/842.5040
E-mail: vy.tran@varian.com

JUN 23 2009

2. Name of the Device:
   Trade / Proprietary Name: PortalVision™ Advanced Imaging
   Common or Usual Name: PortalVision™ Advanced Imaging
   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code: 90 IYE

3. Predicate Device to claim substantial equivalence:
   Varian PortalVision –K003636 and Varian Radiotherapy Imaging System (RTIS) – K971839

4. Description of the Device:

   The PortalVision Advanced Imaging (PVAI) device combines two previously cleared Varian Medical Systems devices into a single device

   The PVAI device provides hardware and software for acquiring MV images and is an accessory to Varian Linear Accelerator devices. The hardware component of PortalVision™ Advanced Imaging consists of a detector support arm known as the R-Arm or Exact Arm, and an image acquisition system that provides high-quality radiographic images and high-energy treatment images. The software component of the modification known as PortalVision™ Advanced Imaging provides additional capability to remotely correct the patient position from the treatment console.

5. Intended Use Statement

   The PortalVision™ Advanced Imaging device is used to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.

6. Indications for Use Statement

   The PortalVision™ Advanced Imaging device is used to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.

7. Substantial Equivalence

   The submission for the PortalVision™ Advanced Imaging device Interface illustrates substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

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

Re: K091209
Trade/Device Name: PortalVision Advanced Imaging
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 23, 2009
Received: April 24, 2009

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VARIAN
medical systems

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304-1038
USA
Tel +1 650 493 4000
www.varian.com

Indications for Use Statement

510(k) Number (if known): K091209

Device Name: PortalVision Advanced Imaging

The PortalVision Advanced Imaging device is used to acquire images of anatomical landmarks, fiducial markers, the shape of the treatment beam and dosimetric signals to guide the delivery of radiation anywhere in the body where radiation treatment is indicated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter _____
(Per 21 CFR § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091209