K042954

MAR 1 1 2005

## 510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the Trilogy Radiotherapy Delivery System

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: October 25, 2004

2. **Name of the Device:**

| | |
|---|---|
| Trade/Proprietary Name: | Vision |
| Common or Usual Name: | Image Database |
| Classification Name: | Radiological Image Processing System<br>21 CFR §892.5840<br>Class II<br>Product Code: 90 LLZ |

3. **Predicate Devices:**

   a. Varis Images including Ximatron Digital Imaging option, K952313
   b. Varis 1.4g, K001643

4. **Description of the Device:**
The name Varis Images has changed to Vision. The Vision product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive plan and image data from diagnositic studies, treatment planning, simulation, plan verification and treatment. Vision also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments.

5. **Intended Use Statement:**
Vision is a plan and image management application that is intended to enable an authorized user to enter, access, modify, store and archive plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. Vision also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments.

6. **Summary of the Technological Characteristics:** The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate device. This chart is located in Tab 9 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2005

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

Re: K042956
Trade/Device Name: Vision™
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Product Code: 90 IYE
Regulation Number: 21 CFR §892.5840
Regulation Name: Radiation therapy stimulation system
Product Code: 90 KPQ
Regulatory Class: II
Dated: February 1, 2005
Received: February 3, 2005

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): K042956
Device Name: Vision

**Indications For Use:**

Vision is designed to assist the radiation therapy staff to prepare and approve treatment plans, and to perform quality assurance of the treatments. The preparation tasks include image acquisition, viewing and manipulation, and treatment plan definition, manipulation and scheduling.

(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 ✓

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042956