JUN 12 1998

K981056

varian
oncology systems

Premarket Notification [510K] Summary
as required by 21 CFR 807.92

Data Summary was prepared:
March 18, 1998

Submitter's Name:
Varian Oncology Systems
3045 Hanover Street
Palo Alto, CA 94304

Contact Person:
Linda S Nash
Regulatory Compliance & Safety
Manager
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Device Name:
Varian Ximatron ScanVision
with Version 5.0 Software

Classification Name:
Radiation Therapy Simulation System

Predicate Device:
Varian Ximatron CT Option
cleared to market per 510(k) No. K910647

Product Description:
The Varian Ximatron ScanVision is an attachment to the Varian Radiation therapy simulator Ximatron. ScanVision is a hardware and software computed tomography acquisition system, based on Varis Images for a Varian Ximiatron radiation therapy simulator. It acquires CT slice information as digital images from the Ximatron simulator. These images may be viewed and manipulated prior to being made available to the doctor for planning the treatment.

In combination with XimaVision, which is an integral part of ScanVision, either:

- the doctor can specify and mark on the flattened fluoro image where he wants the slices to be taken or
- after the slices have been taken, the slice positions can be automatically marked on the fluoro image.

ScanVision is also linked to the Ximitron for automatic set-up of the Ximatron and the X-ray generator for scanning.

Intended Use:
The purpose of the Ximatron ScanVision is to be used to obtain CT images of the patient in the intended treatment position, for the purpose of radiation therapy treatment planning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 1998

Linda S. Nash
Regulatory Compliance & Safety Manager
Varian Oncology Systems
3045 Hanover Street
Palo Alto, CA 94304

Re: K981056
Ximatron Scan Vision
Dated: March 18, 1998
Received: March 23, 1998
Regulatory class: II
21 CFR 892.5840/Procode 90 KPR

Dear Ms. Nash:

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 requirements, 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/dsma/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

varian

Statement of Indications for Use*

I state in my capacity as Manager, Regulatory Compliance and Safety, of Varian Oncology Systems that the Product which is the subject of this premarket notification is intended to be used for the following:

The Varian Ximatron ScanVision CT device is an attachment to the Varian Radiation therapy simulator Ximatron. It is to be used to obtain CT images of the patient in the intended treatment position, for the purposes of radiation therapy treatment planning.

L S Nash

Linda S Nash,
Regulatory Compliance & Safety
Manager

March 18, 1998
Date

*Suggested language and format to meet the requirements of section 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and 21 CFR sections 801.4 and 809.92(a)(5).

K981056
510(k) Number

Linda A. Kepner
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981056

Division Sign-off
Office of Device Evaluation

Prescription Use X over-the-counter Use
(Per 21 CFR 801.109)