

**Summary of
Safety and Effectiveness
Information**

V962950

1. Submitter: Varian Oncology Systems
3045 Hanover Street
Palo Alto, CA 94304

JUL 22 1997

Contact: Charles H. Will, Manager
Regulatory Compliance & Safety
Phone (415) 424-5036
FAX (415) 424-4830
cwill@os.varian.com

Prepared: July 26, 1996

2. Device Name: CADPLAN
Radiation Therapy Treatment Planning (RTP) System

3. Predicate Device: FOCUS, manufactured by
Computerized Medical Systems, Inc.

4. Description: Varian CADPLAN is a comprehensive 3D RTP system for radiation dose modeling of patients undergoing photon or electron therapy or brachytherapy, based on modern UNIX technology. External beam calculation is fully 3-dimensional supporting coplanar and non-coplanar fields. The beam model takes into account collimator rotation, off-center calculation, and irregular field shape. Different energies and treatment modalities (fixed, isocentric, and arc) can be combined in the same plan; and external beam, intracavitary, and interstitial plans can be combined. Wedges, both static and dynamic, blocks, compensators, and boluses can be used. All images, graphical data, and texts are displayed on one high resolution monitor. Easy to use operation is provided with mouse selectable menus.

5. Intended Use: CADPLAN is used to plan radiation therapy treatments employing linear accelerators and other similar teletherapy devices with x-ray energies from 1 to 50 MV, as well as Cobalt-60, and electron energies from 1 to 50 MeV, and to plan brachytherapy treatments. CADPLAN will plan the 3D radiotherapy treatment approaches to combined modality plans, asymmetric and non-coplanar field, total body irradiation, multileaf collimators, motorized and dynamic wedges, customized blocking, compensating filters, and bolus.

5. Intended Use: CADPLAN includes export capabilities to verify beam
Cont'd. and patient data, dose planning results, and provide
on-line information to block-cutting devices.
6. Technological Considerations: CADPLAN has no significant differences in design, materials,
energy source or other technological characteristics compared
to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 1997

Charles H. Will
Manager
Regulatory Compliance & Safety
Varian Oncology Systems
Varian Associates, Inc.
3045 Hanover Street
Palo Alto, California 94304-1129

Re: K962950
Varian Cadplan ver. 2.62, Radiotherapy
Treatment Planning System
Dated: June 30, 1997
Received: July 2, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Will:

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 (Pre-market 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 requirement, 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/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

510(k) Number: K962950

Device Name: Varian CadPlan, Version 2.62

Indications for use:

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

CADPLAN is used to plan radiation therapy treatments employing linear accelerators and other similar teletherapy devices with x-ray energies from 4 to 50 MV, as well as Cobalt-60, and electron energies from 4 to 50 MeV, and to plan brachytherapy treatments. CADPLAN will plan the 3D radiotherapy treatment approaches to combined modality plans, asymmetric and non-coplanar field, total body irradiation, multileaf collimators, motorized and dynamic wedges, customized blocking, compensating filters, and bolus.

CADPLAN includes export capabilities to verify beam and patient data, dose planning results, and provide on-line information to block-cutting devices.

Charles H. Will, Manager
Regulatory Compliance & Safety

Date

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K962950

Prescription Use ✓
(Per 21 CFR 801.109)