AUG - 9 1999

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K984532

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

Date Summary was prepared;
December 18, 1998

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

Contact Person:
Linda S. Nash
Regulatory Compliance & Radiation
Safety Manager
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Device Name:
CadPlan Helios Option 6.0

Classification Name:
Accelerator, Linear, Medical

Predicate Device:
Peacock Plan CORVUS, K940663

Product Description:
CadPlan Helios is an inverse planning tool for creating highly conformal plan using intensity-modulated fields. Inverse planning refers to the process of computing the optimum field intensities for the required numbers of beams to achieve the desired dose of distribution with specified complaints. It allows for creation of in-field intensity profiles that produce the desired dose distribution as precisely as possible.

Varian Associates, Inc. 3045 Hanover Street Palo Alto, California 94304-1129 U.S.A.
650.493.4000 FAX: 650.424.4830

Helios computes the in-field intensities on the basis of specified clinical constraints for the desired dose distribution inside target volumes and critical organs. The calculated intensity profiles are then converted to a pattern of dynamic Multi-Leaf Collimator (MLC) motions. The combination of modulated dose delivery and dynamic MLC motion allows dose to be conformed precisely to anatomical structures. Helios implements the inverse planning algorithm and support of dynamic MLC for Intensity Modulated Radiation Therapy.

Intended Use:
To automatically design the beam profiles that most closely generate the desired dose distribution.

Technological Characteristics:
See the attached "Comparison of Characteristics and Specifications Table".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Linda Nash
Regulatory Affairs & Quality Assurance Manager
Varian Associates, Inc.
3045 Hanover Street
Palo Alto, California 94304-1129

Re: K984532
CadPlan Helios Option 6.0
Dated: May 7, 1999
Received: May 12, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 MUJ

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications For Use

510(k) Number (if known): K984532

Device Name: CadPlan Helios Option 6.0

Indications for Use:

CadPlan is used to plan radiation therapy treatments employing linear accelerators and other similar teletherapy devices and 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.

(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 Use___
(per 21 CFR 801.109)

David A. Clegg
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984532

PARTNERS FOR Life

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