MAY 22 2002

VARIAN
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K021268

Premarket Notification [510(k)] Summary
as required by 21 CFR 807.92

Date summary was prepared:

April 16, 2002

Submitter's Name:

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Person:

Linda S. Nash
Corporate Director, Regulatory Affairs and Quality Assurance
Phone (650) 424-6990
FAX (650) 842-5051
E-mail linda.nash@varian.com

Device Name:

Eclipse, Helios Option

Classification Name:

System, Planning, Radiation Therapy Treatment

Predicate Device:

CadPlan Helios Option Version 6.0, K9845432

Product Description:

Eclipse Helios Option is an inverse planning software used to generate complicated radiation (megavoltage photon) therapy treatment plans for Linear accelerators having dynamic MLC capabilities. The physician defines the desired treatment outcome in terms of dose-volume constraints: Helios uses the dose-volume information to automatically optimize the dose distribution within the patient by modulating the radiation fluences for each treatment field. Helios requires a user interface in order to define the regions of interest within the patient and to add treatment fields to be used for the radiation therapy treatment. Helios 6.5 will use Varian's Eclipse device as the front-end interface to its optimization engine. Varian Eclipse is a computer-based device used for calculating and displaying prospective or verification treatment plans for particular patients undergoing a course of radiation therapy. The system consists of a computer with graphics display, and plotter output.

Eclipse Helios Option is an integral part of the Eclipse (K010975) treatment planning system.

Intended Use:

The Eclipse Helios Option is an inverse planning tool for creating a highly conformal radiation treatment plan using intensity modulated photon fields, and is an option to Eclipse (K010975). Helios creates in-field intensity modulated beam profiles that result in precisely shaped dose distributions inside the patient. Helios computes the in-field intensities based on user-specified clinical dose-volume constraints corresponding to the desired dose distribution inside target volumes and critical organs. Helios implements an inverse planning algorithm and supports dynamic MLC treatments for Intensity Modulated Radiation Therapy (IMRT). The Helios option is used to assist the clinician by shaping and modulating the field intensities according to the clinical constraints and patient anatomy.

Technological Characteristics:

See the attached "Specification Comparison Chart", Tab F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Ms. Linda Nash
Corporate Director, Regulatory Affairs
and Quality Assurance
VARIAN Medical Systems
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K021268
Trade/Device Name: Varian Eclipse, Helios Option 6.5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: April 16, 2002
Received: April 22, 2002

Dear Ms. Nash:

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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K021268

Device Name: ECLIPSE, HELIOS OPTION

Indications For Use:

The Varian Eclipse Helios Option software is used to inversely plan photon radiation therapy treatments employing linear accelerators and other similar teletherapy devices with x-ray energies from 1 – 50 MV.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021268