

K091492

## Premarket Notification 510(k) Summary

**Submitter's Name:**

Varian Medical Systems, Inc.  
3100 Hansen Way E-110  
Palo Alto, CA 94304  
Contact Name: Vy Tran  
Phone: (650) 424-5731  
Fax: (650) 424-5040  
Date: May 2009

JUN 18 2009

**Proprietary Name:**

Eclipse Treatment Planning System

**Classification Name:**

Medical charged-particle radiation therapy system,  
21 CFR §892.5050, ~~MUJ Class II~~

**Common/Usual Name:**

Eclipse TPS

**Predicate Devices:**

Eclipse Treatment Planning System, K073020

**Device Description:**

The Varian Eclipse™ Treatment Planning System (Eclipse TPS) provides software tools for planning the treatment of malignant or benign diseases with radiation. Eclipse TPS is a computer-based software device used by trained medical professionals to design and simulate radiation therapy treatments. Eclipse TPS is capable of planning treatments for external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation, (brachytherapy) treatments.

**Statement of  
Indications for Use:**

The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.

**Technological  
Characteristics:**

Refer to the Substantial Equivalence Comparison Chart.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 18 2009

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

Re: K091492

Trade/Device Name: Eclipse Treatment Planning System  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical Charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: MUJ  
Dated: May 14, 2009  
Received: May 20, 2009

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 (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.

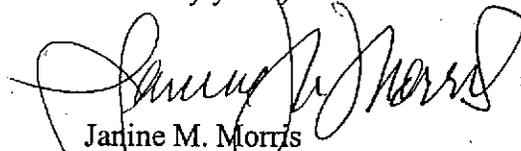
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

# Eclipse Treatment Planning System (TPS)

## Indications for Use

510(k) Number (if known): K091492

Device Name: Eclipse Treatment Planning System

### Indications for Use:

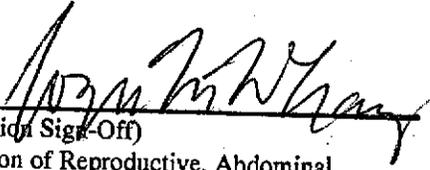
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Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K091492

(Posted November 13, 2003)

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