

DEC 19 2007

## 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: October 24, 2007

**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, K071873

**Device Description:** The Varian Eclipse™ Treatment Planning System (Eclipse TPS) (K071873) 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.

Substantial Equivalence Comparison Chart

Arc Planning was initially cleared as K010975, May 2, 2001

Helios (IMRT optimization) was initially cleared as K021268, May 22, 2002

|                                      | <b>Predicate Device<br/>Eclipse K071873</b>  | <b>Modified Device<br/>Pending 510(k)</b>  |
|--------------------------------------|--|--|
| <b>Indications for Use Statement</b> | 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. | 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. |
| <b>Algorithm Features</b>            | <p>a) IMRT optimization: Fast dose calculation algorithm (Multi-Resolution Dose Calculation, mrdc) used with optimization techniques to produce optimal fluences, then LMC algorithm used to turn those into MLC sequences, finally dose calculation (AAA) to calculate the actual dose cleared in K021268</p> <p>b) Arc fields, i.e. gantry rotation while beam is on cleared in K010975</p>  | Dose Dynamic Arc algorithm produces treatment plans combining Arc and IMRT: Arc fields with IMRT optimization. Optimization uses the same fast dose calculation (mrdc) as previously. The same AAA algorithm (K041403) is used to calculate actual dose. MLC modeling is improved to better account for phenomena related to small MLC openings typical of Dose Dynamic Arc fields.  |
| <b>Other Features</b>                | All other features cleared previously through multiple 510(k)s remain the same and were most recently cleared in the last Eclipse 510(k) clearance K071783   | Remain the same as in the latest clearance K071873   |



DEC 19 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K073020

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: November 21, 2007  
Received: November 26, 2007

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 such 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.

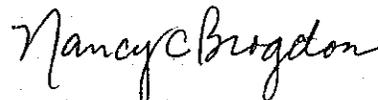
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

|                 |                                  |              |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology)          | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology)                      | 240-276-0120 |
| Other           |                                  | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Nancy C. Brogdon  
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): \_\_\_\_\_

Device Name: Eclipse Treatment Planning System

Indications for Use:

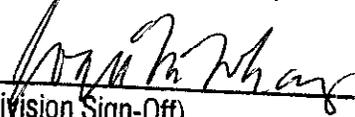
The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments. In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

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

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

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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  K07302 0

(Posted November 13, 2003)

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