K131891
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PREMARKET NOTIFICATION

510(k) Summary

Eclipse Treatment Planning System

As required by 21 CFR 807.92

SEP 25 2013

Submitter's Name:

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto CA94304

Contact Name: Peter J. Coronado
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Fax:650/842.5040
Date: 21 June 2013

Proprietary Name: Eclipse Treatment Planning System

Classification Name: system,planning,radiation therapy treatment
21CFR892.5050, MUJ, Class II

Common/Usual Name: Eclipse, TPS, Eclipse TPS, Eclipse 12,. Eclipse 12 TPS, Eclipse TPS 12.

Predicate Devices: Eclipse Treatment Planning System (K102011)

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.

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.

Changes in Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION (ECLIPSE 10- K102011)	DEVICE WITH CHANGE ECLIPSE 12
Supported External Beams & Accessories	• TrueBeam support	• TrueBeam support
Graphical User Interface	• Nexus Phase 0 – Home screen integration and navigation not present	• Nexus Phase 0 – Home screen integration and navigation
Image Segmentation	• Automatic on-demand and pre-processing tools for multiple organs/structures	• No Automatic on-demand and pre-processing tools for multiple organs/structures • (SmartAdapt) toolset utilizing changed CT-MR and MR-MR deformable registration
Dose Calculation	• Photon calculation o RapidArc: intermediate dose calculation o RapidArc: Varian linac and support o FFF support for TrueBeam o	• Photon calculation o RapidArc: enhancements in intermediate dose calculation o IMRT: intermediate dose calculation o RapidArc Varian linac, and Elekta VMAT support o FFF: Support for C3 and TrueBeam • Dose-Volume Histogram (DVH) Estimation
	• Proton calculation o Modulated scanning (spot scanning) technique o Spot editor	• Proton calculation o Modulated scanning technique (spot *and line* scanning), *support block and MLC* o Range uncertainty feature o Spot editor user interface improvements o Dosimetrically equivalent treatment units (for different gantries) o Block drill bit corrections for milling machines
	• Brachytherapy calculation o AcurosBV dose calculation algorithm o AcurosBV calculates dose to transport media but reports it in water	• Brachytherapy calculation o AcurosBV dose calculation algorithm in 64 bit environment o AcurosBV calculates does to transport media o Nexus phase 0 support

Feature and/or Specification of new/modified device	Cleared Device Feature/Specification (Eclipse 10- K102011)	Device with Change Eclipse 12
	• 64 bit External Beam Planning, BrachyVision and Proton, PRO and AcurosXB algorithms • Fluence calculation by LMC algorithm	• 64 bit External Beam Planning, BrachyVision and Proton, PRO, AcurosXB, AcurosBV and BAO & DVO algorithms and DVH Estimation. • Unified fluence calculation in Eclipse & DCF by the final 3D dose calculation algorithm
Import/Export Interfaces	• Film Scanner import	• No Film Scanner import • Eclipse Scripting API (ESAPI) read only access
Infrastructure	• Sybase Server	• SQL Server migration • Zero Clinical Downtime: Faster DB upgrades • Zero Clinical Downtime: Remote deployment of the clients • Nexus Phase 0 o RT Prescription integration o Plan validation and status change service o Dosimetrically Equivalent machine change service o Approval modifications

Summary of Non-clinical Testing

Verification testing was performed to demonstrate that the performance and functionality of the new and existing features met the design input requirements.

Regression testing was performed to verify the integrity of any changes. Validation testing was performed on a production equivalent device, under clinically representative conditions by qualified personnel.

Conclusion of Non-Clinical testing

Results from Verification and Validation testing demonstrate that the product met defined user needs and defined design input requirements. Varian therefore considers Eclipse 12 to be safe and effective and to perform at least as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director, Regulatory Affairs
911 Hansen Way, M/S E110
PALO ALTO CA 94303

Re: K131891
Trade/Device Name: Eclipse 12 Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, LHN
Dated: June 21, 2013
Received: June 28, 2013

Dear Mr. Coronado:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131891

Device Name: Eclipse 12 Treatment Planning System

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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 IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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