DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 5, 2017

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

Re: K170969
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: June 7, 2017
Received: June 8, 2017

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 Industry and Consumer Education 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" (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/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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170969

Device Name
Eclipse Treatment Planning System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PREMARKET NOTIFICATION

510(k) Summary

Eclipse Treatment Planning System

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado-Director Regulatory Affairs Phone: 650/424.6230 Fax: 650/646.9200 E-mail: submissions.support@varian.com
Proprietary Name:	Eclipse Treatment Planning System
Classification Name:	system,planning,radiation therapy treatment 21CFR892.5050, MUJ, Class II
Common/Usual Name:	Eclipse TPS, Eclipse, Treatment Planning System.
Predicate Devices:	Eclipse Treatment Planning System 13.7 (K152393).
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:

The significant changes compared with the predicate are:

1. Support for treatment planning for Varian RDS radiotherapy treatment units.
2. Scripting is enhanced to include Script Approval and Eclipse Automation.

The complete list of changes and their related requirements can be found in the document "Tracing Changed/New Features to System Requirements" in Section 18 of this submission.

Device Comparison Table

	PREDICATE DEVICE FEATURE/ SPECIFICATION 510(K) ID# K152393 ECLIPSE TPS V13.7	MODIFIED DEVICE FEATURE/ SPECIFICATION ECLIPSE TPS V15.1.1
2. General Usage		
External beam PHOTON planning	Yes	Yes
External beam PHOTON inverse planning	Yes	Yes
External beam ELECTRON planning	Yes	Yes
External beam PROTON planning	Yes	Yes
External beam OCULAR PROTON planning (EOPP)	No *)	No *)
Internal BRACHYTHERAPY planning	Yes	Yes
Stereotactic Frame Localization	Yes	Yes
Treatment Planning for Varian RDS	No	Yes
3. Supported External Beams & Accessories		
Photon beams	Yes	Yes
Electron beams	Yes	Yes
Proton beams	Yes	Yes
Coplanar fields	Yes	Yes
Non-coplanar fields	Yes	Yes
Multi-leaf Collimators	Yes	Yes
Asymmetric collimators	Yes	Yes
Stereotactic Cone collimators	Yes	Yes
Arc fields	Yes	Yes
Poured Blocks	Yes	Yes
Compensators	Yes	Yes
Physical wedges	Yes	Yes
Dynamic wedges	Yes	Yes
Flattening filter free support (FFF)	Yes	Yes
Elekta Versa HD (FFF)	Yes	Yes
Rotating treatment couch	Yes	Yes
Non-rotating RDS couch	No	Yes
Elekta Agility MLC 160	Yes	Yes
Varian SX1 MLC	No	Yes
4. Supported Brachytherapy Sources & Accessories		
Plan for high dose rate afterloader	Yes	Yes

	PREDICATE DEVICE FEATURE/ SPECIFICATION 510(K) ID# K152393 ECLIPSE TPS V13.7	MODIFIED DEVICE FEATURE/ SPECIFICATION ECLIPSE TPS V15.1.1
Manual low dose rate brachytherapy: seeds, line sources, wire	Yes	Yes
Applicator library	Yes	Yes
Needle templates	Yes	Yes
Seed templates	Yes	Yes
5. Graphical User Interface		
Multiple-instance application	Yes	Yes
Multiple-workspace layout	Yes	Yes
Graphical display/editing of field parameters	Yes	Yes
Beam's-Eye-View display	Yes	Yes
3D patient image display	Yes	Yes
Model for human Eye	No *)	No *)
SRS Localization application	Yes	Yes
SRS Planning application	Yes	Yes
Biological Optimization application	Yes	Yes
Biological Evaluation application	Yes	Yes
3D Conformal Optimization application	Yes	Yes
6. Image Processing		
Orthogonal image displays (3)	Yes	Yes
Oblique image display	Yes	Yes
Edge enhancement filters	Yes	Yes
Image smoothing filters	Yes	Yes
CT/MR/PET Image Registration	Yes	Yes
Image blending utility	Yes	Yes
4D image display (registration of time series of 3D images)	Yes	Yes
Digitally reconstructed radiographs	Yes	Yes
Enclosed Volume measurement	Yes	Yes
Stereotactic Frame Coordinate transformation	Yes	Yes
7. Image Segmentation		
Geometrical shapes	Yes	Yes
Manual editing and manipulation tools	Yes	Yes
Automatic /semi-automatic tools	Yes	Yes
Automatic/semi-automatic on-demand and post-processing tools for individual organs/structures	Yes	Yes
Automatic on-demand and pre-processing tools for multiple organs/structures	Yes	Yes
3D Automargin	Yes	Yes
Logical operators	Yes	Yes
Enhanced 2D and 3D contouring tools	Yes	Yes
Enhanced 4D functionality, including structure propagation and display of respiratory amplitude distribution	Yes	Yes
8. Dose Calculation		

	PREDICATE DEVICE FEATURE/ SPECIFICATION 510(K) ID# K152393 ECLIPSE TPS V13.7	**MODIFIED DEVICE FEATURE/ SPECIFICATION ECLIPSE TPS V15.1.1**
Distributed Calculation Framework	Yes	Yes
Photon calculation	**Yes**	Yes
- Energy Range	1 MV – 50 MV	1 MV – 50 MV
- CT-based volumetric calculation	Yes	Yes
- Non-CT based IRREG calculation	Yes	Yes
- Convolution method	Yes	Yes
- Combined electron/photon scatter	Yes	Yes
- Directional heterogeneity correction	Yes	Yes
- Treatment head modelling	Yes	Yes
- Photon Monitor Unit calculation	Yes	Yes
- Compensator monitor unit calculation	Yes	Yes
- Beam Angle Optimization (GEOS)	Yes	Yes
- Leaf Motion Sequencing	Yes	Yes
- Dose Dynamic Arc planning	Yes	Yes
- Cone Dose Calculation	Yes	Yes
- Biological optimization	Yes	Yes
- 3D Conformal Optimization	Yes	Yes
- IMRT optimization	Yes	Yes
- AcurosXB dose calculation algorithm	Yes	Yes
- AAA	Yes	Yes
- Range Uncertainty feature for photons	Yes	Yes
- Siemens mArc	Yes	Yes
- Siemens FFF (unflattened beam)	Yes	Yes
- Elekta Agility MLC 160	Yes	Yes
- RaySearch PlanConverter	Yes	Yes
- Varian SX1 MLC	No	Yes
- FTDC Imaging dose calculation for RDS machine	No	Yes
Electron calculation	**Yes**	Yes
- Energy Range	1 MeV – 50 MeV	1 MeV – 50 MeV
- Gaussian Pencil Beam Model	Yes	Yes
- Electron Monte Carlo algorithm v2	Yes (including Siemens, Elekta)	Yes (including Siemens, Elekta)
- Electron Monitor Unit calculation	Yes	Yes
- Portal Dose Image Prediction	Yes	Yes
Proton calculation	**Yes**	**Yes**
- Energy Range	50 MeV - 300 MeV	50 MeV - 300 MeV
- Single scattering technique	Yes	Yes
- Double scattering technique	Yes	Yes

	PREDICATE DEVICE FEATURE/ SPECIFICATION 510(K) ID# K152393 ECLIPSE TPS V13.7	MODIFIED DEVICE FEATURE/ SPECIFICATION ECLIPSE TPS V15.1.1
- Uniform scanning technique	Yes	Yes
- Modulated scanning technique	Yes	Yes
- Optimization for modulated scanning	Yes	Yes
- Monitor unit calculation for modulated scanning	Yes	Yes
- Range uncertainty feature for Protons	Yes	Yes
- Robust Proton Optimization	Yes	Yes
- AcurosPT Dose Calculation Algorithm	Yes	Yes
Brachytherapy calculation	**Yes**	**Yes**
- AAPM TG 43 compliant	Yes	Yes
- Point Dose calculation	Yes	Yes
- Optimization to point dose constraints	Yes	Yes
- Geometric optimization	Yes	Yes
- AcurosBV dose calculation algorithm	Yes (with support for report the dose to medium)	Yes (with support for report the dose to medium)
- Intermediate dose capability for AcurosBV algorithm	Yes	Yes
- Solid applicator model support	Yes	Yes
Eclipse Algorithm Application Programming Interface (EAAPI)	Yes	Yes
RapidPlan - Dose Volume Histogram (DVH) Estimation	Yes (extended Dose Volume Histogram (DVH) Estimation)	Yes (extended Dose Volume Histogram (DVH) Estimation)
9. Dose evaluation		
Dose color wash	2D, 3D	2D, 3D
Isodose levels	2D, 3D	2D, 3D
Isodose Surface	3D	3D
Reference point dose summary	Yes	Yes
Dose Volume Histogram plot	Yes	Yes
Plan summing tool	Yes	Yes
Plan comparison tools	Yes	Yes
Evaluation using biological models	Yes	Yes
10. Plan Output – Hardcopy		
Graphics window screen dump	Yes	Yes
Patient administration data	Yes	Yes
Plan parameters	Yes	Yes
Geometrical displays of plan data	Yes	Yes
Dose distribution	Yes	Yes
DVH plot	Yes	Yes
BEV display	Yes	Yes
Patient orientation	Yes	Yes
User Configurable hardcopy layouts	Yes	Yes

	PREDICATE DEVICE FEATURE/ SPECIFICATION 510(K) ID# K152393 ECLIPSE TPS V13.7	MODIFIED DEVICE FEATURE/ SPECIFICATION ECLIPSE TPS V15.1.1
11. Import/Export Interfaces		
ARIA RadOnc integration	Yes	Yes
DICOM RT	Yes	Yes
Other image formats	Yes	Yes
Electromagnetic Digitizer	Import	Import
Film Scanner	no	no
Eclipse Scripting API (ESAPI) read only access	yes (includes also BrachyVision and Proton)	yes (includes also BrachyVision and Proton)
Eclipse Scripting API (ESAPI) write access	Yes (in research database, only, with additional proton planning support)	Yes (in research database, only, with additional proton planning support)
Eclipse Automation	No	Yes
Export field coordinates to Laser System	export	export
Basic RT Prescription information available	Yes	Yes

***** A compatible feature has not been released and using the feature is blocked either by not including it in the distribution media for the indicated version(s) or by licensing**.**

Non-clinical Testing

Verification and Validation were performed for all the new features and regression testing was performed against the existing features of Eclipse. System requirements created or affected by the changes can be traced to the test outcomes.

Conclusion of Non-Clinical testing

The outcome was that the product conformed to the defined user needs and intended uses and that there were no DRs (discrepancy reports) remaining which had a priority of Safety Intolerable or Customer Intolerable. Varian therefore considers Eclipse 15.1.1 to be safe and effective and to perform at least as well as the predicate device.

Argument for Substantial Equivalence to the Predicate Device

A subset of features of the current device is different to the predicate. Of these, the significant changes compared with the predicate are associated with support for treatment planning for Varian RDS radiotherapy treatment units and Eclipse Automation.

These changes are all considered by Varian to be enhancements of the predicate. The Indications for Use and the Intended Use remain unchanged. There are no changes in the principle of operation of the software. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes that Eclipse TPS is substantially equivalent to the predicate.