

K133247
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PREMARKET NOTIFICATION

510(k) Summary

FEB - 7 2014

Eclipse Treatment Planning System

As required by 21 CFR 807.92

Submitter's Name:

Varian Medical Systems
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Palo Alto CA94304

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Date: 3rd October 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, Treatment Planning System.

Predicate Devices:

Eclipse Treatment Planning System 12 (K131891)

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 in this device are those associated with the change to the Proton optimizer, modifications to the Proton Dose Calculation algorithm, Proton Layer by Layer MLC support and the Improved second source modeling in AAA and AXB.

Device Comparison Table
(Changed Features are in bold).

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PREDICATE DEVICE K131891 ECLIPSE 12	DEVICE WITH CHANGE ECLIPSE 13
General usage	<ul style="list-style-type: none"> • External beam PHOTON planning • External beam PHOTON inverse planning • External beam ELECTRON planning • External beam PROTON planning • External beam OCULAR PROTON planning • Internal BRACHYTHERAPY planning • Stereotactic Frame Localization 	<ul style="list-style-type: none"> • External beam PHOTON planning • External beam PHOTON inverse planning • External beam ELECTRON planning • External beam PROTON planning • External beam OCULAR PROTON planning • Internal BRACHYTHERAPY planning • Stereotactic Frame Localization
Supported External Beams & Accessories	<ul style="list-style-type: none"> • Photon beams • Electron beams • Proton beams • Coplanar fields • Non-coplanar fields • Multi-leaf Collimators • Asymmetric collimators • Stereotactic Cone collimators • Arc fields • Poured Blocks • Compensators • Physical wedges • Dynamic wedges • Flattening filter free support (FFF) • Rotating treatment couch • TrueBeam 1.5 support • TrueBeam 1.6 support. 	<ul style="list-style-type: none"> • Photon beams • Electron beams • Proton beams • Coplanar fields • Non-coplanar fields • Multi-leaf Collimators • Asymmetric collimators • Stereotactic Cone collimators • Arc fields • Poured Blocks • Compensators • Physical wedges • Dynamic wedges • Flattening filter free support (FFF) • Rotating treatment couch • TrueBeam 1.5 support • TrueBeam 1.6 and 2.0 support. Support for LE imaging (2.5X for imaging only) and support for new portal imager.
Supported Brachytherapy Sources & Accessories	<ul style="list-style-type: none"> • Plan for high dose rate afterloader • Manual low dose rate brachytherapy: seeds, line sources, wire • Applicator library • Needle templates 	<ul style="list-style-type: none"> • Plan for high dose rate afterloader • Manual low dose rate brachytherapy: seeds, line sources, wire • Applicator library • Needle templates
Graphical User Interface	<ul style="list-style-type: none"> • Multiple-instance application • Multiple-workspace layout • Graphical display/editing of field parameters • Beam's-Eye-View display • 3D patient image display • Model for human Eye • SRS Localization application • SRS Planning application • Biological Optimization application • Biological Evaluation application • 3D Conformal Optimization application • Nexus Phase 0 – Home screen integration and navigation 	<ul style="list-style-type: none"> • Multiple-instance application • Multiple-workspace layout • Graphical display/editing of field parameters • Beam's-Eye-View display • 3D patient image display • Model for human Eye • SRS Localization application • SRS Planning application • Biological Optimization application • Biological Evaluation application • 3D Conformal Optimization application • Nexus Phase 0 – Home screen integration and navigation • Limited RT Prescription information available in Eclipse
Image Processing	<ul style="list-style-type: none"> • Orthogonal image displays (3) • Oblique image display • Edge enhancement filters • Image smoothing filters • CT/MR/PET Image Registration 	<ul style="list-style-type: none"> • Orthogonal image displays (3) • Oblique image display • Edge enhancement filters • Image smoothing filters • CT/MR/PET Image Registration

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PREDICATE DEVICE K131891 ECLIPSE 12	DEVICE WITH CHANGE ECLIPSE 13
	<ul style="list-style-type: none"> • Image blending utility • 4D image display (registration of time series of 3D images) • Digitally reconstructed radiographs • Enclosed Volume measurement • Stereotactic Frame Coordinate transformation 	<ul style="list-style-type: none"> • Image blending utility • 4D image display (registration of time series of 3D images) • Digitally reconstructed radiographs • Enclosed Volume measurement • Stereotactic Frame Coordinate transformation
Image Segmentation	<ul style="list-style-type: none"> • Geometrical shapes • Manual editing and manipulation tools • Automatic /semi-automatic tools • Automatic/semi-automatic on-demand and post-processing tools for individual 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 • 3D Automargin • Logical operators 	<ul style="list-style-type: none"> • Geometrical shapes • Manual editing and manipulation tools • Automatic /semi-automatic tools • Automatic/semi-automatic on-demand and post-processing tools for individual 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 • Separate Selection Workspace and enhanced Contouring • 3D Automargin • Logical operators
Dose Calculation	<ul style="list-style-type: none"> • Distributed Calculation Framework • Photon calculation <ul style="list-style-type: none"> ○ Energy Range: 1 MV – 50 MV ○ CT-based volumetric calculation ○ Non-CT based IRREG calculation ○ Convolution method ○ Combined electron/photon scatter ○ Directional heterogeneity correction ○ Treatment head modeling ○ Photon Monitor Unit calculation ○ Compensator monitor unit calculation ○ Beam Angle Optimization (GEOS) ○ Leaf Motion Sequencing ○ Dose Dynamic Arc planning ○ Cone Dose Calculation ○ Biological optimization ○ 3D Conformal Optimization ○ IMRT optimization ○ AcurosXB dose calculation algorithm ○ RapidArc: enhancements in intermediate dose calculation ○ IMRT: intermediate dose calculation ○ RapidArc Varian linac, and Elekta VMAT support ○ FFF: Support for C3 and TrueBeam ○ Dosimetrically equivalent machines • SmartIMRTDose-Volume Histogram (DVH) Estimation* 	<ul style="list-style-type: none"> • Distributed Calculation Framework • Photon calculation <ul style="list-style-type: none"> ○ Energy Range: 1 MV – 50 MV ○ CT-based volumetric calculation ○ Non-CT based IRREG calculation ○ Convolution method ○ Combined electron/photon scatter ○ Directional heterogeneity correction ○ Treatment head modeling ○ Photon Monitor Unit calculation ○ Compensator monitor unit calculation ○ Beam Angle Optimization (GEOS) ○ Leaf Motion Sequencing ○ Dose Dynamic Arc planning ○ Cone Dose Calculation ○ Biological optimization ○ 3D Conformal Optimization ○ IMRT optimization ○ AcurosXB dose calculation algorithm ○ RapidArc: enhancements in intermediate dose calculation ○ IMRT: intermediate dose calculation ○ RapidArc Varian linac, and Elekta VMAT support ○ FFF: Support for C3 and TrueBeam ○ Dosimetrically equivalent machines ○ Plan uncertainty for photon plans ○ Isocenter handling improvements ○ Addition of Point Dose functionality into AAA dose calculation algorithm ○ Improved second source modeling in AAA and AXB
	<ul style="list-style-type: none"> • Electron calculation <ul style="list-style-type: none"> ○ Energy Range: 1 MeV – 50 MeV 	<ul style="list-style-type: none"> • Electron calculation <ul style="list-style-type: none"> ○ Energy Range: 1 MeV – 50 MeV

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PREDICATE DEVICE K131891 ECLIPSE 12	DEVICE WITH CHANGE ECLIPSE 13
	<ul style="list-style-type: none"> ○ Gaussian Pencil Beam Model ○ Electron Monte Carlo algorithm ○ Electron Monitor Unit calculation ○ Dosimetrically equivalent machines • Proton calculation <ul style="list-style-type: none"> ○ Energy Range: 50 MeV - 300 MeV ○ Single scattering technique, support block and MLC ○ Double scattering technique, support block and MLC ○ Uniform scanning technique, support block and MLC ○ Modulated scanning technique (spot and line scanning), support block and MLC ○ Single scattering technique ○ Optimization for modulated scanning ○ Monitor unit calculation for modulated scanning ○ Range uncertainty feature ○ Spot editor user interface improvements ○ Dosimetrically equivalent treatment units (for different gantries) ○ Block drill bit corrections for milling machines 	<ul style="list-style-type: none"> ○ Gaussian Pencil Beam Model ○ Electron Monte Carlo algorithm ○ Electron Monitor Unit calculation ○ Dosimetrically equivalent machines • Proton calculation <ul style="list-style-type: none"> ○ Energy Range: 50 MeV - 300 MeV ○ Single scattering technique, support block and MLC ○ Double scattering technique, support block and MLC ○ Uniform scanning technique, support block and MLC ○ Modulated scanning technique (spot and line scanning), support block and MLC ○ Single scattering technique ○ Optimization for modulated scanning ○ Monitor unit calculation for modulated scanning ○ Range uncertainty feature ○ Spot editor user interface improvements ○ Dosimetrically equivalent treatment units (for different gantries) ○ Support for Sumitomo tx machine with Layer-by-Layer MLC ○ Non-linear universal proton optimizer ○ PCS enhancements ○ Block drill bit corrections for milling machines
	<ul style="list-style-type: none"> • Brachytherapy calculation <ul style="list-style-type: none"> ○ AAPM TG 43 compliant ○ Point Dose calculation ○ Optimization to point dose constraints ○ Geometric optimization ○ AcurosBV dose calculation algorithm in 64 bit environment ○ AcurosBV calculates doses to transport media ○ Nexus phase 0 support ** 	<ul style="list-style-type: none"> • Brachytherapy calculation <ul style="list-style-type: none"> ○ AAPM TG 43 compliant ○ Point Dose calculation ○ Optimization to point dose constraints ○ Geometric optimization ○ AcurosBV dose calculation algorithm in 64 bit environment ○ AcurosBV calculates doses to transport media and reports dose to transport media ○ Addition of TG186 source model and standard applicator for AcurosBV ○ Nexus phase 0 support ○ Source model approval ○ Enhanced Normal Tissue and Source Fitting ○ Simple contouring tools in Planning workspace ○ Nominal Time Constraints in Volumetric Optimizer ○ New version of AcurosBV algorithm <ul style="list-style-type: none"> ▪ Dose tracking support ▪ Ability to calculate AcurosBV on non-CT image

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PREDICATE DEVICE K131891 ECLIPSE 12	DEVICE WITH CHANGE ECLIPSE 13
	<ul style="list-style-type: none"> • Eclipse Algorithm Application Programming Interface (EAAPI) • 64 bit External Beam Planning, BrachyVision and Proton, PRO, AcurosXB, AcurosBV and BAO & DVO algorithms • Unified fluence calculation in Eclipse & DCF by the final 3D dose calculation algorithm 	<ul style="list-style-type: none"> • Eclipse Algorithm Application Programming Interface (EAAPI) • 64 bit External Beam Planning, BrachyVision and Proton, PRO, AcurosXB, AcurosBV and BAO & DVO algorithms • Unified fluence calculation in Eclipse & DCF by the final 3D dose calculation algorithm
Dose evaluation	<ul style="list-style-type: none"> • Dose color wash 2D, 3D • Isodose levels 2D, 3D • Isodose Surface 3D • Reference point dose summary • Dose Volume Histogram plot • Plan summing tool • Plan comparison tools • Evaluation using biological models 	<ul style="list-style-type: none"> • Dose color wash 2D, 3D • Isodose levels 2D, 3D • Isodose Surface 3D • Reference point dose summary • Dose Volume Histogram plot • Plan summing tool • Plan comparison tools • Evaluation using biological models
Plan Output – Hardcopy	<ul style="list-style-type: none"> • Graphics window screen dump • Patient administration data • Plan parameters • Geometrical displays of plan data • Dose distribution • DVH plot • BEV display • Patient orientation • User Configurable hardcopy layouts 	<ul style="list-style-type: none"> • Graphics window screen dump • Patient administration data • Plan parameters • Geometrical displays of plan data • Dose distribution • DVH plot • BEV display • Patient orientation • User Configurable hardcopy layouts
Import/Export Interfaces	<ul style="list-style-type: none"> • ARIA RadOnc integration • DICOM RT • Other image formats • Electromagnetic Digitizer import • No Film Scanner import • Eclipse Scripting API (ESAPI) read only access • Export field coordinates to Laser System 	<ul style="list-style-type: none"> • ARIA RadOnc integration • DICOM RT • Other image formats • Electromagnetic Digitizer import • No Film Scanner import • Eclipse Scripting API (ESAPI) read only access <i>including brachytherapy plans, write access in non-clinical system</i> • Export field coordinates to Laser System
Infrastructure	<ul style="list-style-type: none"> • SQL Server migration • Zero Clinical Downtime: Faster DB upgrades • Zero Clinical Downtime: Remote deployment of the clients • Nexus Phase 0 <ul style="list-style-type: none"> ○ RT Prescription integration ○ Plan validation and status change service ○ Dosimetrically Equivalent machine change service ○ Approval modifications 	<ul style="list-style-type: none"> • SQL Server migration • Zero Clinical Downtime: Faster DB upgrades • Zero Clinical Downtime: Remote deployment of the clients • Nexus Phase 0 <ul style="list-style-type: none"> ○ RT Prescription integration ○ Plan validation and status change service ○ Dosimetrically Equivalent machine change service ○ Approval modifications • <i>Unicode support</i> • <i>Electronic acceptance of Customer Approval Tests</i> • <i>MD5 checksums in dose calculation related files, e.g. dose matrix</i>

*For business reasons this feature is not being commercialized at this time.

** Nexus is a project involving the Aria product. Aria is not part of this submission

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 13 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 changes to the Proton Optimizer, modifications to the Proton Dose Calculation algorithm, introduction of Proton Layer by Layer MLC support, and the improved second source modeling in AAA and AXB. Other changes are related to dose calculations and scripting for Brachytherapy, image segmentation, import and export interfaces and infrastructure.

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.



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

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

February 7, 2014

Re: K133247

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: October 3, 2013
Received: November 4, 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,



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): K133247

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
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 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)

Michael D. O'Hara