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K133227
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VARIAN
medical systems

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October 18, 2013

510(k) Summary

The information below is provided for the Smart Segmentation Knowledge Based Contouring, following the format of 21 CFR 807.92.

1. 510(k) Owner: Varian Medical Systems
   3100 Hansen Way, M/S C 260
   Palo Alto, CA 94304
   Contact Name: Peter J. Coronado - Director, Regulatory Affairs
   Phone: 650/424.6320
   Fax: 650/842.5040
   E-mail: submissions.support@varian.com

2. Name of the Device: Smart Segmentation Knowledge Based Contouring
   Trade/Proprietary Names: Smart Segmentation – Knowledge Based Contouring

   Common Name: Smart Segmentation Knowledge Based Contouring

   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code 90 IYE

3. Predicate Devices: Eclipse K102011
   Smart Segmentation Knowledge Based Contouring K112778

4. Description of the Device:

   The Smart Segmentation Knowledge Based Contouring was most recently cleared as the Varian Smart Segmentation Knowledge Based Contouring, K112778.

   Smart Segmentation - Knowledge Based Contouring is a software only product that provides a combined atlas and model based approach to automated segmentation of structures together with tools for manual contouring or editing of structures. A library of already contoured expert cases is provided which is searchable by anatomy, staging, or free text. Users also have the ability to add or modify expert cases to suit their clinical needs. Expert cases are registered to the target image and selected

structures propagated. Smart Segmentation Knowledge Based Contouring supports inter and intra user consistency in contouring. This product also provides an anatomy atlas which gives examples of delineated organs for the whole upper body, as well as anatomy images and functional description for selectable structures.

5. Reason for submission:

   Changes in SS-KBC have prompted a new submission. Support of 4D-CT data sets and a new algorithm for segmentation of the mandible are changes new to Smart Segmentation Knowledge Based Contouring.

6. Intended Use Statement

   Smart Segmentation - Knowledge Based Contouring provides a combined atlas and model based approach for automated and manual segmentation of structures including target volumes and organs at risk to support the radiation therapy treatment planning process.

7. Indications for Use Statement

   Smart Segmentation Knowledge Based Contouring provides a combined atlas and model based approach for automated and manual segmentation of structures including target volumes and organs at risk to support the radiation therapy treatment planning process.

8. Substantial Equivalence

   The modified device, the Smart Segmentation Knowledge Based Contouring, is substantially equivalent to the predicate devices, the Smart Segmentation Knowledge Based Contouring (K112778) and Eclipse (K102011). The Intended Use and Indications for Use are unchanged.

   Compared with the predicate devices, the Smart Segmentation Knowledge Based Contouring (K112778) and Eclipse with Smart Segmentation (K102011), the basic operation and technological characteristics are the same. Operational differences are described in the Instructions for Use for the SS-KBC 2.1. A comparison table illustrating the substantial equivalence of the modified device to the predicate devices appears below.

Changes in Technological characteristics:

Feature List	Eclipse (K102011)	Smart Segmentation – KBC 2.0 (K112778)	Smart Segmentation – KBC 2.1
General Usage			
Support for External beam PHOTON planning	yes	yes	yes
Support for External beam PHOTON inverse planning	yes	yes	yes
Support for External beam ELECTRON planning	yes	yes	yes
Support for External beam PROTON planning	yes	yes	yes
Automated Structure Delineation	yes	yes	yes
Graphical User Interface			
Three View Layout	yes	yes	yes
Four View Layout (ortho & 3d)	yes	yes	yes
3d volume rendering	yes	yes	yes
3d volume MIP rendering	yes	yes	yes
3d volume MIP (rotating) rendering	yes	yes	yes
3d mesh rendering	yes	yes	yes
3d multiplane rendering single image	yes	yes	yes
3d multiplane rendering blended image	yes	yes	yes
3d segments rendering	yes	yes	yes
Pixel Info Tool	yes	yes	yes
Distance Tool	yes	yes	yes
Pan Image	yes	yes	yes
Adjust window / level	yes	yes	yes
Angle Tool	yes	yes	yes
Area Profile Tool	yes	yes	yes
Histogram Tool	yes	yes	yes
Select Structure Tool	yes	yes	yes
Planar Contour Drawing Tool	yes	yes	yes
Brush Tool	yes	yes	yes
Diffusion Brush Tool	yes	yes	yes
Volumetric Contour Drawing Tool	yes	yes	yes
Deform Structure Tool	no	yes	yes
Image Threshold Tool	yes	yes	yes
PET Subvolume Threshold Tool	yes	yes	yes
Boolean Structure Operations	yes	yes	yes

Feature List	Eclipse (K102011)	Smart Segmentation – KBC 2.0 (K112778)	Smart Segmentation – KBC 2.1
Auto Match 3d (rigid)	yes	yes	yes
Manual Match (rigid)	yes	yes	yes
Automatic Deformable Registration	no	yes	yes
Region of interest selection	yes	yes	yes
Body Search Tool	yes	no	yes
Post-processing Tool (smoothing)	yes	no	yes
Add Margins Tool	yes	no	yes
High Density Tool	yes	no	yes
Flood Fill Tool	yes	no	yes
Extract Wall Tool	yes	no	yes
Structure templates	yes	no	yes
4D-CT: player	yes	no	yes
4D-CT: merge structures	yes	no	yes
4D-CT: paste structures to all phases	yes	no	yes
4D-CT: automatic segmentation	yes	no	yes
4D-CT: RPM respiration trace viewer	no	no	yes
Structure Editing			
Clear Structure	yes	yes	yes
Delete Structure	yes	yes	yes
Delete Structure Set	yes	yes	yes
Copy Structure to registered image	yes	yes	yes
Duplicate structure	yes	yes	yes
Set Structure Status	yes	yes	yes
Change Structure ID	yes	yes	yes
Change Structure color & Style	yes	yes	yes
Show PET Patient Data	yes	yes	yes
Crop structure	yes	no	yes
Extend Segmentation	yes	no	yes
Interpolate Segmentation	yes	no	yes
Structure Segmentation and Expert Case Selection			
Default to algorithm based segmentation for certain structures	yes (algorithm based is only option)	yes	yes
Expert Case browser	no	yes	yes
Expert case search - filters	no	yes	yes
Expert case search - free text search	no	yes	yes

Feature List	Eclipse (K102011)	Smart Segmentation – KBC 2.0 (K112778)	Smart Segmentation – KBC 2.1
Expert case search - add / remove bookmarks	no	yes	yes
Expert opinion text display	no	yes	yes
Add new customer case to database	no	yes	yes
Modify existing expert case on database	no	yes	yes
Generate thumbnail preview for expert case	no	yes	yes
Anatomy text book display	no	yes	yes
Expert Case Library content and supported structures			
Segmentation of mandible	no	no	yes
Connectivity			
DICOM compatibility	yes	yes	yes

9. 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.

10. Conclusions from 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 Smart Segmentation Knowledge Based Contouring 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

March 14, 2014

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

Re: K133227
Trade/Device Name: Smart Segmentation - Knowledge Based Contouring
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 31, 2014
Received: February 3, 2014

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" (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 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): K133227

Device Name: Smart Segmentation Knowledge Based Contouring

Indications for Use:

Smart Segmentation Knowledge Based Contouring provides a combined atlas and model based approach for automated and manual segmentation of structures including target volumes and organs at risk to support the radiation therapy treatment planning process.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k) ___K133227___