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

Varian Medical Systems, Inc.
% Mr. Peter Coronado
Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94303

September 5, 2014

Re: K141248
Trade/Device Name: Smart Segmentation – Knowledge Based Contouring
Regulation Number: 21CFR 892.5050
Regulation Name: Medical charged particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: July 22, 2014
Received: July 23, 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): K141248

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 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

510(k) _____K141248_____

K141248

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May 7, 2014

**Summary 510(k)**

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: 650/646.9200
   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 MUJ

3. Predicate Devices: Smart Segmentation Knowledge Based Contouring K133227

4. Description of the Device:

   The Smart Segmentation Knowledge Based Contouring was most recently cleared as the Varian Smart Segmentation Knowledge Based Contouring, K133227.

   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 Device:

Changes in SS-KBC have prompted a new submission. Semi-automatic segmentation of lung tumors and sorting of expert cases based on similarity of image are changes new to Smart Segmentation Knowledge Based Contouring.

New Features Table

| Segmentation Tools |
|---|
| New Lung tumor segmentation tool |
| Calypso beacon detection tool allows automated detection and Segmentation of implanted Calypso beacons. |
| Expert case Browser |
| Expert Case browser has been redesigned to allow retrieving Expert Cases based on similarity to clinical case. |
| It is easier to select a segmentation algorithm used to contour a structure. |
| Expert case library |
| New expert cases for Nasopharynx, Tonsil, Base of Tongue, Hypopharynx, Larynx. |
| Controlled Structure Terminology |
| SS-KBC contains a structure dictionary. The use of the structure dictionary allows identifying a structure by assigning a standardize label. The assigned label is uniquely matched to computer readable code, enabling effective data mining and exchange of knowledge models between systems using different naming schemes. |
| The structure creation in SS-KBC starts with a label search. The selected ID populates the structure ID, color and type. The structure ID can be edited and serves as custom structure name which will be displayed through the system (including the Expert Case Library). The default structure IDs can be changed in the RT Administration workspace. In order to ensure interoperability between systems which do not implement structure codes and labels, it is recommended to maintain the default IDs. |

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

Compared with the predicate devices, the Smart Segmentation Knowledge Based Contouring (K133227), the basic operation and technological characteristics are the same. Operational

differences are described in the Instructions for Use for the SS-KBC 13.5. Also, the Intended Use and Indications for Use are unchanged.

The new features table lists the new features of Smart Segmentation Knowledge Based Contouring, as compared to the predicate device. The features of the predicate device are many while there are only a few added. Therefore Varian concludes the modified device, the Smart Segmentation Knowledge Based Contouring, is substantially equivalent to the predicate device, the Smart Segmentation Knowledge Based Contouring (K133227).

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.