Varian Medical Systems Inc.  
April 19, 2021

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

Re:  K203469

Trade/Device Name:  AI Segmentation  
Regulation Number:  21 CFR 892.5050  
Regulation Name:  Medical Charged-Particle Radiation Therapy System  
Regulatory Class:  Class II  
Product Code:  MUJ  
Dated:  March 18, 2021  
Received:  March 19, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

[Signature]

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K203469

Device Name
AI Segmentation

Indications for Use (Describe)
AI Segmentation uses CT images to segment patient anatomy for use in radiation therapy treatment planning. AI Segmentation utilizes a pre-defined set of organ structures in the following regions: head and neck, thorax, pelvis, abdomen. Segmentation results are subject to review and editing by qualified, expert radiation therapy treatment planners. Results of AI Segmentation are utilized in the Eclipse Treatment Planning System where it is the responsibility of a qualified physician to further review, edit as needed, and approve each structure.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) SUMMARY

The following information is provided as required by 21 CFR 807.92.

SUBMITTER

Name and Address: Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto, CA 94304

Contact Person: Peter J. Coronado
Sr. Director, Regulatory Affairs
Phone: 650-424-6320 | Fax: 650-646-9200
submissions.support@varian.com

Date Prepared: 18 March 2021

DEVICE

Subject Device Name: AI Segmentation
Common/Usual Name: medical image segmentation software
Product Code and Classification: Medical charged-particle radiation therapy system
MUJ | 21 CFR 892.5050 | Class II

PREDICATE DEVICE

Predicate Device Name: Smart Segmentation Knowledge Based Contouring v2.2 (K141248)
Reference Device: Ethos Treatment Planning v1.0 (K192377)

Note: Referenced for the use of existing, established methods to evaluate performance of AI-based algorithms and technology

DEVICE DESCRIPTION

AI segmentation is a web-based application, running in the cloud, that provides a combined deep learning and classical-based approach for automated segmentation of organs at risk, along with tools for structure visualization. This software medical device product is used by trained medical professionals and consists of a web application user interface where the results from the automated segmentation can be reviewed and selected for export into the compatible treatment planning system. AI Segmentation is not intended to provide clinical decisions, medical advice, or evaluations of radiation plans or treatment procedures.

INDICATIONS FOR USE

AI Segmentation uses CT images to segment patient anatomy for use in radiation therapy treatment planning. AI Segmentation utilizes a pre-defined set of organ structures in the following regions: head and neck, thorax, pelvis, abdomen. Segmentation results are subject to review and editing by qualified, expert radiation therapy professionals.
treatment planners. Results of AI Segmentation are utilized in the Eclipse Treatment Planning System where it is the responsibility of a qualified physician to further review, edit as needed, and approve each structure.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The new device, referred to as the “subject device” throughout this summary, is release version v1.0 (version 1.0) of AI Segmentation. The subject device has some technological and functional similarity and differences with the predicate device, Smart Segmentation Knowledge Based Contouring version v2.2 (K141248).

At a high level, both the predicate device and the subject device are based on the same characteristics:

- Both devices are software-only medical devices.
- Both devices are intended for use by medical professionals within the context of supporting radiotherapy treatment planning.
- Both devices contain automated segmentation algorithms used to process radiological images in order to generate contouring of structures for a variety of anatomical sites.
- Both devices include review interfaces and tools for users to independently assess the output.
- Both devices are compatible with the Eclipse Treatment Planning System, which is Varian’s radiotherapy treatment planning software.

The significant differences in the subject device compared with the predicate device are:

1. Use of AI-based algorithms for automated segmentation and contouring
   a. Note: These algorithms are static and non-adaptive; they do not alter their behavior over time based on user input.
2. Cloud deployment and hosting of software components and algorithms
3. Absence of manual editing or contouring tools

**PERFORMANCE DATA**

The following performance data was provided in support of the substantial equivalence determination.

**Software Verification and Validation Testing**

Software verification and validation testing was conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern.

Test results demonstrate conformance to applicable requirements and specifications.

No animal studies or clinical tests have been included in this pre-market submission.

**Standards Conformance**

The subject device conforms in whole or in part with the following standards that address software development, safety, and usability:

- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
• IEC 62366-1 Edition 1.0 2015-02 Application of usability engineering to medical devices
• IEC 62083 Edition 2.0 2009-09 Requirements for the safety of radiotherapy treatment planning systems
• IEC 82304-1 Edition 1.0 2016-10 Health software - Part 1: General requirements for product safety

**Argument for substantial equivalence to the predicate device**
A subset of software features and characteristics of the subject device are different from the predicate device. However, Varian considers these differences to be enhancements of the predicate, while the principle of operation of the subject device is the same as that of the existing predicate device. Verification and validation testing demonstrate that the subject device performs its intended use as designed through the product’s functional, usability, and safety requirements. Varian therefore believes that the subject device is substantially equivalent to the predicate device.

**CONCLUSION**
The predicate device was cleared based only on non-clinical testing, and no animal or clinical studies were performed for the subject device. The non-clinical data supports the safety of the device, and verification and validation testing demonstrate that the subject device should perform as intended in the specified use conditions. There were no remaining discrepancy reports (DRs) which could be classified as Safety or Customer Intolerable.

Therefore, Varian considers **AI Segmentation** to be substantially equivalent to the predicate device, **Smart Segmentation Knowledge Based Contouring (K141248)**.