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

Re: K211881
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: June 17, 2021
Received: June 21, 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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211881

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

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:	27 August 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:	AI Segmentation (K203469)

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, edited, 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 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 modified device, referred to as the "subject device" throughout this summary, is version 2.0 of **AI Segmentation**. The predicate device is version 1.0 of **AI Segmentation**, previously cleared under K203469.

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. Added and updated some AI models 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. Added simple editing tools for users

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.

Non-clinical Testing and Performance Evaluation of Algorithms

The submission includes non-clinical performance tests for automated contouring AI models that are updates to classical algorithms in the predicate device and other AI models that contour new additional structures. Performance evaluation of these algorithms followed the same approach used by the predicate device version.

Each AI model was assessed using the DICE similarity index as a comparative measure of the auto-generated contours against ground truth contours for a given structure. Aggregated DICE scores for each AI model were then compared to literature values or against the performance of the prior model when evaluating an update to an existing algorithm. Clinical experts also evaluated the performance of these AI models during validation testing. A qualitative scoring system was used to measure the acceptability of auto-generated contours, with a target of 80% of expert scores designating the contours as "acceptable with minor or no adjustments".

Based on these test criteria, AI models in the subject device exhibited equivalent performance to the predicate.

Overall 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** (version 2.0) to be substantially equivalent to the predicate device, **AI Segmentation** (version 1.0).