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

February 12, 2021

Re: K203766
Trade/Device Name: 4D Integrated Treatment Console v13.0 MR4
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: December 22, 2020
Received: December 23, 2020

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 and Part 809); 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)*
K203766

Device Name
4D Integrated Treatment Console v13.0 MR4

Indications for Use *(Describe)*
The 4D Integrated Treatment Console provides assistance for accurate treatment delivery for each patient by monitoring linear accelerator parameters and by preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan.

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.

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.

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510(k) Summary

The following information is provided as required by 21 CFR 807.92

K203766

SUBMITTER

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

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

Date Prepared: December 22, 2020

DEVICE

Subject Device Name: 4D Integrated Treatment Console v13.0 MR4

Common/Usual Name: 4D Integrated Treatment Console

Product Code and Classification: Medical charged-particle radiation therapy system
MUJ | 21 CFR 892.5050 | Class II

PREDICATE DEVICE

Predicate Device Name: 4D Integrated Treatment Console v13.0 (K133331)

Reference Device(s): No reference devices were used in this submission

DEVICE DESCRIPTION

4D Integrated Treatment Console (4DITC) allows the user to retrieve treatment plans and images from the Oncology Information System (OIS) and send the plan and images to the Treatment Console System (TCS). The planned treatment parameters from the OIS are verified against the TCS delivery parameters for accuracy. All treatment parameters on the TCS must match the treatment parameters on the 4DITC before treatment can be delivered. After the treatment has been completed for the session, the user closes the session and treatment history is sent to the OIS to be recorded. The recorded treatment history can then be displayed and reviewed in the OIS.

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INDICATIONS FOR USE

The 4D Integrated Treatment Console provides assistance for accurate treatment delivery for each patient by monitoring linear accelerator parameters and by preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified device, referred to as the "subject device" throughout this summary, is release version v13.0 MR4 (Version 13.0 Minor Release 4) of the 4D Integrated Treatment Console with additional software changes incorporated since the release version of the predicate device, v13.0 (version 13.0; K133331).

The **Changes** in the subject device compared with the predicate device are as follows:

- Risk control measure of accidentally treating with a Quality Assurance (QA) / verification plan changed from a warning message to blocking the use of QA / verification plans for treatment in clinical mode
- Shared Framework Integration
- Microsoft Windows Embedded Standard (WES) 7 Support
- IGMA 8913 workstation updated to IGMA 8110D
- Cybersecurity Enhancements
    - WES7 Knowledge Base (KB) updates
    - Application whitelisting (Applocker)
    - USB mass storage hardening
    - MICAP firmware upgrade
- Minor enhancements and bug fixes

PERFORMANCE DATA

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

Software Verification and Validation Testing

Software verification and validation were 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.

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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:

- IEC 62304:2006+A1:2015 Medical device software – Software lifecycle processes
- IEC 62366-1:2015 Medical device – Part 1: Application of usability engineering to medical devices
- IEC 61217:2011 Radiotherapy Equipment – Coordinates, Movements and Scales
- IEC 62274:2005 Medical electrical equipment – Safety of radiotherapy record and verify systems

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 verification and validation data demonstrates that the subject device should perform as intended in the specified use conditions.

Therefore, Varian considers the subject device, **4D Integrated Treatment Console v13.0 MR4,** is substantially equivalent to the predicate device **4D Integrated Treatment Console v13.0 (K133331).**