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

July 31, 2019

Re: K191761
Trade/Device Name: Mobius3D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 28, 2019
Received: July 1, 2019

Dear Mr. Peter 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 M. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191761

Device Name
Mobius3D v2.2

Indications for Use *(Describe)*
Mobius3D software is used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy. It calculates radiation dose three-dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data. Patient alignment and anatomy analysis is based on read-in treatment planning images (such as computed tomography) and read-in daily treatment images (such as registered cone beam computed tomography).
Mobius3D is not a treatment planning system. It is only to be used by trained radiation oncology personnel as a quality assurance tool.

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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K191761

Premarket Notification 510(k) Summary

As required by 21 CFR 807.92

Special 510(k) Submission for Mobius3D v2.2

Submitter's Name	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA 94304 Contact Name: Peter J. Coronado Phone: 650/424.6320 Fax: 650/646.9200 Date: June 2019
Proprietary Name	Mobius3D
Classification Name	Accelerator, Linear, Medical 21 CFR 892.5050 Class II Product Code: IYE
Common/Usual Name	Mobius3D
Predicate Devices	Mobius3D (v2.0.0) K153014
Indications for Use	Mobius3D software is used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy. It calculates radiation dose three-dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data. Patient alignment and anatomy analysis is based on read-in treatment planning images (such as computed tomography) and read-in daily treatment images (such as registered cone beam computed tomography). Mobius3D is not a treatment planning system. It is only to be used by

	trained radiation oncology personnel as a quality assurance tool.
Device Description	Mobius3D (v. 2.2) is a software product used within a radiation therapy clinic for quality assurance and treatment plan verification. It is important to note that while Mobius3D operates in the field of radiation therapy, it is neither a radiation delivery device (e.g. a linear accelerator), nor is it a treatment planning system (TPS). Mobius3D cannot design or transmit instructions to a delivery device, nor does it control any other medical device. Mobius3D is an analysis tool meant solely for quality assurance (QA) purposes when used by trained medical professionals. Being a software-only QA tool, Mobius3D never comes into contact with patients. Mobius3D performs dose calculation verifications for radiation treatment plans by doing an independent calculation of radiation dose. Radiation dose is initially calculated by a treatment planning system (TPS), which is a software tool that develops a detailed set of instructions (i.e. a plan) for another system (e.g. a linear accelerator) to deliver radiation to a patient. The dose calculation performed by Mobius3D uses a proprietary collapsed cone convolution superposition (CCCS) algorithm. Mobius3D also performs dose delivery quality assurance for radiation treatment plans by using the measured data recorded in a linear accelerator's delivery log files to calculate a delivered dose. This is presented to the end user in a software component of Mobius3D called MobiusFX. The MobiusFX component is available to users through licensing as an add-on to the core Mobius3D software features. Mobius3D performs quality assurance of a patient's alignment and anatomy analysis. This analysis is based on comparison of Cone Beam Computed Tomography (CBCT) images taken immediately before treatment to the images used for treatment planning, which are typically acquired using standard Computed Tomography (CT). This analysis is presented to the end user in an add-on software module within Mobius3D called CBCT Checks.

Device Comparison and Technological Characteristics

The significant changes compared with the predicate device are as follows:

1. Support for Varian Halcyon Added
2. Dose Calculation Reimplemented in C

The other modifications to the software device were considered to be non-significant changes. The complete list of changes are in the Summary of Testing for Changed or New Features and also addressed in the device comparison table in the Executive Summary and Substantial Equivalence Discussion.

Performance Data

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

Software verification and validation 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.

The subject device conforms in whole or in part with the following standards:

• IEC 62304:2006, Medical Device Software - Software Life Cycle Processes

• IEC 62366-1:2015, Medical Devices - Part 1: Application of Usability Engineering to Medical Devices

• IEC 61217:2011, Radiotherapy Equipment - Coordinates, Movements, and Scales

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

Conclusions

The non-clinical data support the safety of the device and the software verification and validation demonstrate that subject device should perform as intended in the specified use conditions. Varian considers Mobius3D v2.2 to be safe and effective and to perform as well or better than the predicate device.