Varian Medical Systems Inc. July 10, 2019
Peter Coronado
Director, Varian Oncology Systems Regulatory Affairs
911 Hansen Way
Palo Alto, California 94304

Re: K190137
Trade/Device Name: Identify
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: January 25, 2019
Received: January 29, 2019

Dear 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 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)*
K190137

Device Name
Identify

Indications for Use *(Describe)*
IDENTIFY is indicated for patient and accessory identification, positioning and tracking for imaging and radiation therapy treatments.

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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PREMARKET NOTIFICATION

510(k) Summary

Identify

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA94304 Contact Name: Peter J. Coronado-Director Regulatory Affairs Phone: 650/424.6320 Fax: 650/646.9200 E-mail: submissions.support@varian.com Date: 25th January 2019.
Proprietary Name:	Identify
Classification Name:	Medical charged-particle radiation therapy system 21CFR892.5050, IYE, Class II
Common/Usual Name:	Patient identification & positioning/tracking system
Predicate Device:	Identify (K112692)
Device Description:	Identify is used for patient-setup, guidance and to monitor a patient before and during radiation treatment. The system consists of cameras, software, PC workstations, RFID kit, Interlock unit, calibration tools, Palm scan unit, RFID tags and optical markers, network components and cabling and handheld controllers.
Intended Use	IDENTIFY is intended for patient and accessory identification, positioning and tracking for imaging and radiation therapy treatments.
Indications for Use:	IDENTIFY is indicated for patient and accessory identification, positioning and tracking for imaging and radiation therapy treatments.

Significant differences:

There are no significant differences compared to the predicate. This submission is to account for cumulative differences.

Non-clinical Testing

Hardware and software verification and validation testing was conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards listed below. Test results showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Software verification and validation testing 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, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on this medical device. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Standards Conformance

Identify conforms to the following FDA recognised standards. For full details refer to document: "Standards Introduction" in Section 9 of this submission.

IEC 62304:2006
ISO 15223-1:2012
IEC 60601-1:2005+A1:2012
IEC 60601-1-2:2014
IEC 61217:2011
ISO 10993-1:2009/(R)2013,
AAMI RT2:2017
ISO 14971:2007
IEC 62366-1 (IEC 62366:2007+A1:2014)

Identify also complies with the following non-FDA recognised standards.

ISO 13485:2012

Conclusion of Non-Clinical testing

The outcome was that the product conformed to the defined user needs and intended uses and that there were no DRs (discrepancy reports/Unresolved Anomalies) remaining which had a priority of Safety Intolerable or Customer Intolerable. Varian therefore considers Identify to be safe and effective and to perform at least as well as the predicate device.

Argument for Substantial Equivalence to the Predicate Device

A subset of technological characteristics and features of the current device is different to the predicate. These differences are all considered by Varian to be enhancements of the predicate. There are no changes in the principle of operation of the device. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes that Identify is substantially equivalent to the predicate.