DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 12, 2016

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

Re: K162476
Trade/Device Name: Varian High Energy Linear Accelerator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 10, 2016
Received: November 14, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162476

Device Name
Varian High Energy Linear Accelerator

Indications for Use *(Describe)*
The Varian High Energy Linear Accelerator is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

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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Premarket Notification [510(k)] Summary

Varian High Energy Linear Accelerator

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: September 2, 2016
Name of the Device: **Trade/ Proprietary Names:**	Varian High Energy Linear Accelerator Novalis Tx, Trilogy, Trilogy Tx Clinac iX, Clinac Cx Clinac 2100C, 2100 C/D, 2300 C/D Clinac 21 EX, 23 EX Clinac DHX, DMX
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050, Class II Product Code: IYE
Common/Usual Name:	Medical Linear Accelerator
Predicate Device:	Varian High Energy Linear Accelerator K131807
Device Description:	The Varian High Energy Linear Accelerator models provide various selections among the features, specifications, and accessories that have been most recently cleared as the Varian High Energy Linear Accelerator, K131807. The High Energy Linear Accelerator is a radiotherapy treatment unit. The equipment consists of a gantry, couch, stand and control console. The device is permanently installed. The radiotherapy treatment beam is generated by a linear accelerator assembly consisting of an electron gun, waveguide and collimator. The High Energy (HE) Linear Accelerator device is modified to provide a yield monitoring capability, which triggers an interlock in response to detected beam deviations when specific target hardware anomalies are present. The yield monitoring capability provides an additional check for unexpected changes in radiation beam output, beyond the existing beam checks and dosimetry interlocks provided by the dual ion chamber design. The purpose of the yield monitoring capability is to prevent an undetected decrease in dose output, which can occur in the case of failures within the target hardware. If such hardware failures are present, the yield monitoring capability triggers an interlock and treatment is prevented if 6X, 6FFF, or 6SRS beams do not meet specified output limits. For additional detail please see the Description of Modifications included in the

	submission. The Primary Position Readout (PRO) and Secondary Position Readout (SPRO) are enhanced by the addition of a firmware check for polarity mismatch. The function of the PRO and SPRO remains unchanged. The enhancement provides a secondary check of the positions reported by the PRO and SPRO for all motion axes: jaws, gantry, couch and collimator. The firmware enhancement is an improvement that verifies the polarity of both the PRO and SPRO components, and notifies the user in the case of a polarity mismatch. Notifications continue until the polarity has been corrected. All other features and technological characteristics of the Varian High Energy Linear Accelerator models remain as cleared by K131807.
Intended Use Statement	The Varian High Energy Linear Accelerator is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated
Indications for Use Statement	The Varian High Energy Linear Accelerator is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Technological Characteristics:

Performance Data:

Software Verification and Validation Testing
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.

Clinical Tests No clinical tests have been included in this pre-market submission

Conclusions
The non-clinical data support the safety of the device and the software verification and validation demonstrate that the High Energy Linear Accelerator device with the new yield interlock functionality and firmware check for polarity mismatch performs as intended. Varian therefore considers the High Energy Linear Accelerator to be safe and effective and to perform at least as well as the predicate devices.