



June 28, 2018

Varian Medical Systems, Inc.
Peter J. Coronado
Director, Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K181404

Trade/Device Name: Varian High Energy Linear Accelerator, UNIQUE, Varian Multileaf Collimator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: May 25, 2018
Received: May 29, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181404

Device Name

Varian High Energy Linear Accelerator,
UNIQUE,
Varian Multileaf Collimator (MLC)

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.

The UNIQUE is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

The Varian Multileaf Collimator is intended to assist the clinician in the delivery of external beam radiation to defined target volumes during radiosurgery and radiotherapy while sparing surrounding normal tissue and critical organs from excess radiation.

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)

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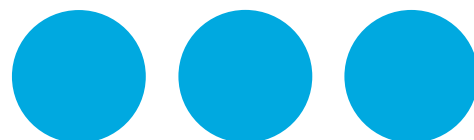
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Premarket Notification 510(K) Summary

The following information is provided according to 21 CFR 807.92.

| | | | | |
|---|--|--|---|--|
| Submitter: | <p>Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304</p> <p>Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 E-mail: submissions.support@varian.com</p> <p>Date Prepared: May 25, 2018</p> | | | |
| Trade/ Proprietary Names: | <p><u>Varian High Energy Linear Accelerator</u></p> <ul style="list-style-type: none"> • 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 <p><u>UNIQUE</u></p> <ul style="list-style-type: none"> • UNIQUE Power Edition • UNIQUE Performance Edition <p><u>Varian Multileaf Collimator (MLC)</u></p> <ul style="list-style-type: none"> • Millennium 52-leaf Multileaf Collimator • Millennium 80-leaf Multileaf Collimator • Millennium 120-leaf Multileaf Collimator • High-Definition 120 Multileaf Collimator (HD120 MLC) | | | |
| | <p><u>Varian High Energy Linear Accelerator, UNIQUE, Varian Multileaf Collimator (MLC)</u></p> <table border="1" data-bbox="342 1528 1471 1902"> <tr> <td data-bbox="342 1528 813 1902"> <p>Classification Name: Medical Charged Particle Radiation Therapy System, 21 CFR §892.5050</p> <p>Common/Usual Name: Medical Linear Accelerator</p> <p>Regulatory Class: Class II</p> <p>Product Code: IYE</p> </td> <td data-bbox="818 1528 1471 1902"> <p>Predicate Devices:</p> <p><u>Varian High Energy Linear Accelerator</u> (Version 9.1, K162476)</p> <p><u>UNIQUE</u> (Version 9.1, K132705)</p> <p><u>Varian Multileaf Collimator</u> (Version 8.0, K133240)</p> </td> </tr> </table> | | <p>Classification Name: Medical Charged Particle Radiation Therapy System, 21 CFR §892.5050</p> <p>Common/Usual Name: Medical Linear Accelerator</p> <p>Regulatory Class: Class II</p> <p>Product Code: IYE</p> | <p>Predicate Devices:</p> <p><u>Varian High Energy Linear Accelerator</u> (Version 9.1, K162476)</p> <p><u>UNIQUE</u> (Version 9.1, K132705)</p> <p><u>Varian Multileaf Collimator</u> (Version 8.0, K133240)</p> |
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| | | |
|--|---|--|
| Device Description: | <u>Varian High Energy Linear Accelerator</u> | |
| | <p>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.</p> <p>All other features and technological characteristics of the Varian High Energy Linear Accelerator models remain as cleared by K162476.</p> | |
| | <u>UNIQUE</u> | |
| | <p>The UNIQUE 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.</p> <p>All other features and technological characteristics of the UNIQUE models remain as cleared by K132705.</p> | |
| | <u>Varian Multileaf Collimator (MLC)</u> | |
| | <p>The Varian Multileaf Collimator (MLC) is an accessory X-ray collimator designed to be mounted on a Varian radiotherapy linear accelerator. The MLC head is mounted on a Varian Linear Accelerator, where it shapes the radiation beam before it is delivered to the patient. The MLC head is permanently bolted onto the casting that holds the X-Jaws and Y-Jaws of the Varian Linear Accelerator gantry.</p> <p>All other features and technological characteristics of the Varian Multileaf Collimator (MLC) models remain as cleared by K133240.</p> | |
| Intended/ Indications For Use Statement: | <i>The indications for use and the intended use are identical in the subject devices as for the predicate.</i> | |
| | <u>Varian High Energy Linear Accelerator</u> | |
| | Intended Use | Indications for Use |
| | 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 | 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. |
| | <u>UNIQUE</u> | |
| | Intended Use | Indications for Use |
| | The UNIQUE is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. | The UNIQUE is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. |
| | <u>Varian Multileaf Collimator (MLC)</u> | |
| | Intended Use | Indications for Use |
| The Varian Multileaf Collimator is intended to assist the clinician in the delivery of external beam radiation to defined target volumes during radiosurgery and radiotherapy while sparing surrounding normal tissue and critical organs from excess radiation. | The Varian Multileaf Collimator is intended to assist the clinician in the delivery of external beam radiation to defined target volumes during radiosurgery and radiotherapy while sparing surrounding normal tissue and critical organs from excess radiation. | |

This bundled Special 510(k) submission provides detail on one significant change and its impact on three Varian devices so they could be addressed during one review; Varian High Energy Linear Accelerator, UNIQUE, and Multileaf Collimator (MLC). The indications for use and the intended use are identical in the subject devices as for the predicate.

Note: The Varian High Energy Linear Accelerator and UNIQUE devices are referred to as **Clinac Console** and Varian Multileaf Collimator (MLC) is referred to as **MLC Controller**.

Significant Difference

The significant difference compared to the predicate devices is:

- Architecture Change: The **Clinac Console** and **MLC Controller** has a new integrated hardware platform known as **CCMC** and the software is ported to support **CCMC** using *VxWorks operating system*

The **High Energy Linear Accelerator** and **UNIQUE Clinac Console** software, *C-Series version 9.5*, **Multileaf Collimator (MLC)** software, *MLC version 8.5* is ported to support the new hardware platform CCMC.

The complete list of new risks and modified risks to **High Energy Linear Accelerator, UNIQUE, and Varian Multileaf Collimator (MLC)** are documented in “*Summary of testing for Significant Change*” in Section 18 of this submission.

| | Device Trade Names or Proprietary names | Predicate | This 510(k) Submission |
|--|--|--|---|
| Varian High Energy Linear Accelerator | Novalis Tx, Trilogy, Trilogy Tx, Clinac iX, Clinac CX Clinac 2100C, Clinac 2100 C/D, Clinac 2300 C/D Clinac 21 EX, Clinac 23 EX Clinac DHX, Clinac DMX | K162476 (Clinac console software referred to as C-Series v9.1) | Clinac Console software referred to as C-Series v9.5 |
| UNIQUE | UNIQUE Power Edition UNIQUE Performance Edition | K132705 (Clinac console software referred to as C-Series v9.1) | Clinac Console software referred to as C-Series v9.5 |
| Varian Multileaf Collimator (MLC) | Millennium 52-leaf Multileaf Collimator Millennium 80-leaf Multileaf Collimator Millennium 120-leaf Multileaf Collimator High-Definition 120 Multileaf Collimator (HD120 MLC) | K133240 (MLC controller software referred to as MLC v8.0) | MLC controller software referred to as MLC v8.5 |

Performance Data

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 all three devices was considered as a “major” level of concern.

The modified devices **High Energy Linear Accelerator, UNIQUE, and Varian Multileaf Collimator (MLC)** are substantially equivalent to the predicate devices *K162476, K132705, and K133240* respectively. Compared with the predicate device, the basic operation and technological characteristics are the same.

Operational differences are described in the Instructions for Use and accompanying user documentation. The indications for use and the intended use for each device are identical.

The subject devices conform in whole or in part with standards provided in Section 09 of this submission. For those recognized standards in which there are clauses that are not applicable, Summary Reports with justifications have been included in the submission.

Summary of Non-Clinical Tests

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

Verification testing was performed to demonstrate that the performance and functionality of the new **C-Series** operating system and **MLC controller** existing features met the design input requirements for **CCMC**.

Regression testing was performed to verify the integrity of any changes. Validation testing was performed on production equivalent devices, under clinically representative conditions by qualified personnel.

Conclusion

The non-clinical data for **CCMC** supports the safety of the devices and the software verification and validation demonstrate that the subject devices should perform as intended in the specified use conditions. Varian therefore considers the **High Energy Linear Accelerator, UNIQUE, and Varian Multileaf Collimator (MLC)** to be safe and effective and to perform at least as well as the predicate devices.