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.
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](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/)) and CDRH Learn ([http://www.fda.gov/Training/CDRHLearn](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](http://www.fda.gov/DICE)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert 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)
K181032

Device Name
Halcyon

Indications for Use (Describe)
Halcyon is indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated for adults and pediatric patients.

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PREMARKET NOTIFICATION

510(k) Summary

Halcyon

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: 6th April 2018

Proprietary Name: Halcyon

Classification Name: Medical charged-particle radiation therapy system
21CFR892.5050, IYE, Class II

Common/Usual Name: Medical Linear Accelerator

Predicate Devices: Halcyon (K170817)

Device Description: Halcyon is a single energy medical linac designed to deliver Image Guided Radiation Therapy and Radiosurgery, using Intensity Modulated and Volumetric Modulated Arc Therapy techniques. It consists of the accelerator and patient support within a radiation shielded treatment room and a control console outside the treatment room.

Intended Use

The Halcyon radiotherapy delivery system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

The intended use is the same as the predicate.

Indications for Use:

Halcyon is indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated for adults and pediatric patients.

Significant differences:

The significant differences compared to the predicate are:

• kV Imaging for improved visualization of soft tissue.
• 0.5cm Definition MLC to potentially enable greater conformity at the isocenter.
• Dynamically Flatten ed Beam using the upper bank of leaves of the MLC to allow forward planning of basic static treatment apertures in combination with a flattened beam.
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

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

IEC 60601-1-3 Edition 2.1 2013-04
AAMI/ ANSI ES60601-1: 2005
IEC 60601-1-6: 2013
IEC 60601-2-1: 2014
IEC 60825-1 Ed. 2.0 2007
IEC 60976 Ed. 2.0 2007
IEC 61217: 2011
IEC 62274: 2005
IEC 62304: 2006
AAMI / ANSI / IEC 62366:2007/(R)2013
ISO 10993-1:2009
IEC 60601-2-68:2014
ISO 15223-1:2012
EN ISO 14971:2012

Halcyon also complies with the following non FDA recognised standards.
IEC 60601-2-68:2014
EN 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) remaining which had a priority of Safety Intolerable or Customer Intolerable. Varian therefore considers Halcyon 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. The Intended Use and indications for use are unchanged. 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 Halcyon is substantially equivalent to the predicate.