



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

June 27, 2017

Re: K170817
Trade/Device Name: Halcyon
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 26, 2017
Received: May 30, 2017

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

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

Indications for Use

510(k) Number (if known)

K170817

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.

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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: 650/424.6230
Fax: 650/646.9200
E-mail: submissions.support@varian.com
Date: 26th May 2017

Proprietary Name: Halcyon

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

Common/Usual Name: Medical Linear Accelerator

Predicate Devices: TrueBeam 2.7 (K162472).

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:

- Multi-leaf collimator (MLC) consists of two sets of opposed leaf banks that are stacked. The upper leaf bank replaces beam-limiting movable jaws.
- Ring design of gantry and stand; moving gantry parts are enclosed within panels
- One Treatment Energy and MV Imaging Energy: 6MV, Flattening Filter Free
- 3 Degrees of Freedom of couch movement, compared with 4 or 6 in the predicate.

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 standards. For full details refer to document: "Introduction to Standards Conformance Forms and Summary Reports."

AAMI/ ANSI ES60601-1: 2005
IEC 60601-1-2: 2007 & 2014
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

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 remains unchanged. There are no new sites or tumor types listed in the Indications for Use compared with 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 Halcyon is substantially equivalent to the predicate.