K131807
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VARIAN
medical systems

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June 17, 2013

OCT 11 2013

510(k) Summary

The information below is provided for the Varian High Energy Linear Accelerator, following the format of 21 CFR 807.92.

1. 510(k) Owner: Varian Medical Systems
   3100 Hansen Way, M/S C 260
   Palo Alto, CA 94304
   Contact Name: Peter J. Coronado - Director, Regulatory Affairs
   Phone: 650/424.6320
   Fax: 650/842.5040
   E-mail: submissions.support@varian.com

2. Name of the Device: Varian High Energy Linear Accelerator
   Trade/Proprietary Names: 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

   Common Name: Medical Linear Accelerator

   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code 90 IYE

3. Predicate Device: Varian High Energy Linear Accelerator K112839

4. Description of the Device:

   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, K112839.

   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.

An extensive system of interlocks is designed to prevent or terminate beam-on unless essential treatment parameters are in place and system operating conditions relevant to safe operation are correct.

The changes to the Varian High Energy Linear Accelerator establish motion zone rules, which limit the motions of couch and gantry that can be initiated or directed from outside the treatment room. The purpose of the zone rules is to increase patient safety by reducing the possibility of collision between the gantry and the patient.

All other features and technological characteristics of the Varian High Energy Linear Accelerator models remain as cleared by K112839.

5. 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.

6. 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.

7. Substantial Equivalence

The modified device, the Varian High Energy Linear Accelerator, is substantially equivalent to the predicate device, the Varian High Energy Linear Accelerator (K112839).

The functionality of the Varian High Energy Linear Accelerator is equivalent to the functionality of the Varian predicate device in safety and effectiveness. The design control procedures applied to the development of the Varian High Energy Linear Accelerator and its modifications include requirements reviews, risk analysis, and verification and validation testing. The results of verification and validation activities demonstrate that the acceptance criteria have been met.

Compared with the predicate device, the Varian High Energy Linear Accelerator (K112839), the basic operation and technological characteristics are the same. Operational differences are described in the Instructions for Use for the Varian High Energy Linear Accelerator. The intended use for the device is unchanged.

A comparison table illustrating the substantial equivalence of the modified device to the predicate device appears below.

FEATURE AND/OR SPECIFICATION	CLEARED DEVICE (HIGH ENERGY LINEAR ACCELERATOR K112839)	DEVICE WITH CHANGE (HIGH ENERGY LINEAR ACCELERATOR)
Intended 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.	Unchanged
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.	Unchanged
Release version of control software	C-Series 9.0	C-Series 9.1
Gantry and couch rotation from outside the treatment room are prevented or limited within Exclusion Zone areas defined by Zone Rules.	No	Yes
Maximum rate at which dose delivery occurs for 10x photon energy	600 MU per minute	600 MU per minute
Maximum rate at which dose delivery occurs for 10x FFF photon energy	2400 MU per minute	2400 MU per minute
Maximum rate at which dose delivery occurs for 6x SRS photon energy	1000 MU per minute	1000 MU per minute
Maximum rate at which dose delivery occurs for 6x FFF photon energy	1400 MU per minute	1400 MU per minute

FEATURE AND/OR SPECIFICATION	CLEARED DEVICE (HIGH ENERGY LINEAR ACCELERATOR K112839)	DEVICE WITH CHANGE (HIGH ENERGY LINEAR ACCELERATOR)
Maximum field size	3D Conformal Radiation Therapy: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm	3D Conformal Radiation Therapy: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm
Maximum allowable dose limit for fixed X treatment type (for non-SRS and non-FFF treatment types)	1999 MU	1999 MU
Maximum programmable dose	9999 MU	9999 MU

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, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

October 11, 2013

Re: K131807
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: October 2, 2013
Received: October 8, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Michael D. O'Hara for

Janine M. Morris
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): K131807

Device Name: Varian High Energy Linear Accelerator

Indications for Use:

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Richard D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K131807_____