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K132705
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VARIAN
medical systems

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304-1038
USA
Tel +1 650 493 4000
www.varian.com

August 27, 2013

510(k) Summary

The information below is provided for the UNIQUE, 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: UNIQUE
   Trade/Proprietary Names: UNIQUE Power Edition
   UNIQUE Performance Edition

   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: UNIQUE K101751

4. Description of the Device:

   The UNIQUE was most recently cleared as the Varian UNIQUE, K101751.

   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.

   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 UNIQUE 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 UNIQUE remain as cleared by K101751.

5. Intended Use Statement

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.

6. Indications for Use Statement

The UNIQUE 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 UNIQUE, is substantially equivalent to the predicate device, the UNIQUE (K101751). The Intended Use and Indications for Use are unchanged.

Compared with the predicate device, the UNIQUE (K101751), the basic operation and technological characteristics are the same. Operational differences are described in the Instructions for Use for the UNIQUE. A comparison table illustrating the substantial equivalence of the modified device to the predicate device appears below.

Changes in Technological characteristics:

Feature and/or Specification	**CLEARED DEVICE (UNIQUE K101751)**	**DEVICE WITH CHANGE (UNIQUE)**
C-Series Software release version	8.0	9.1
Dose Rates (MU/minute) - Photons - Electrons	 100 – 600 none	 100 – 600 none
Energy Levels - Photons - Electrons	 6 MV none	 6 MV none
Arc Therapy - Photons - Electrons	 Standard none	 Standard none

Feature and/or Specification	CLEARED DEVICE (UNIQUE K101751)	DEVICE WITH CHANGE (UNIQUE)
Couch	Exact Couch IGRT Couch Top	Exact Couch IGRT Couch Top
RapidArc (Varian VMAT)	Optional	Optional
Multileaf Collimator	Standard	Optional
PortalVision – MV Imaging System	Standard	Optional
4D Integrated Treatment Console	Standard	Standard
Real-Time Position Management (RPM)	Optional	Optional
Collision protection between the Gantry & couch, when the couch is outside the boundary conditions set by the user	For gantry rotation from outside the treatment room, motion rules are enforced when the imaging arm is extended.	For gantry rotation from outside the treatment room, motion rules are enforced whether the imaging arm is extended or retracted.
Extended Travel Range Zone includes the 10 cm additional height needed to support the Third-party Prone Breast Couch Insert	No	Yes
Interlock preventing additional dose from being delivered after beam hold has been set	Hardware control	Hardware control plus additional secondary software check
Gantry and Couch rotation from outside the treatment room are prevented or limited within Exclusion Zone areas defined by Zone Rules.	No	Yes

8. Summary of Non-Clinical Testing

Verification testing was performed to demonstrate that the performance and functionality of the new and existing features met the design input requirements.

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

9. Conclusions from Non-Clinical testing

Results from Verification and Validation testing demonstrate that the product met defined user needs and defined design input requirements. Varian therefore considers UNIQUE to be safe and effective and to perform at least as well as the predicate device.

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 J. Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

October 31, 2013

Re: K132705
Trade/Device Name: UNIQUE
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: August 27, 2013
Received: August 29, 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 warrantics. 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" (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 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): K132705

Device Name: UNIQUE

Indications For Use:

The Varian UNIQUE 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K132705_____