K071360

Premarket Notification 510(k) Summary

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: (650) 424-5731
Fax: (650) 424-5040
Date: May 11, 2007

JUN - 8 2007

Proprietary Name: Optical Guidance Platform

Classification Name: Medical charged-particle radiation therapy system, 21 CFR 892.5050, 90 IYE, Class II

Common/Usual Name: Optical Guidance Platform

Predicate Devices:
SNT Stereotactic Localization System, K971675
SNT Linac Accessories, K971893
Patient Positioning System, K980750
Biteblock Localization and Positioning System, K981346
Head/Neck Application, K994355
RadioCameras Extracranial System, K000246

Device Description: The Optical Guidance Platform provides a method of positioning the patient for either radiosurgery or radiotherapy by using high precision infrared camera to detect the location of the stereotactic localization device comprised of infrared markers (either LED's or reflective markers) attached to the patient or stereotactic immobilization device. It is designed to provide patient positioning for intracranial and extracranial targets. It also provides an option for ultrasound tracking of soft tissue to more accurately define the target in extracranial radiosurgery and radiotherapy.

Statement of Indications for Use: Varian Medical System's Optical Guidance Platform (OGP) is for use with a charged particle accelerator to perform precise positioning of treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial or extracranial lesions.

Technological Characteristics: Refer to the Substantial Equivalence Comparison Chart.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 8 2007

Ms. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K071360
Trade/Device Name: Optical Guidance Platform
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 11, 2007
Received: May 15, 2007

Dear Ms. Tran:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071360

Device Name: Optical Guidance Platform

Indications for Use:

Varian Medical System's Optical Guidance Platform (OGP) is for use with a charged particle accelerator to perform precise positioning of treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial or extracranial lesions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071360

(Posted November 13, 2003)