MAY 21 2003

K030534

Premarket Notification [510K] Summary as required by 21 CFR 807.92

Date Summary was prepared:

February 14, 2003

Submitter's Name:

Varian Medical Systems
3100 Hansen Way E-110
Palo Alto, CA 94304

Contact Person:

Linda S. Nash
Corporate Director, Regulatory Affairs and Quality Assurance
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Device Name:

VariSeed 7.1

Classification Name:

Source, Brachytherapy, Radionuclide

Predicate Device:

VariSeed 7.0 (K982821), BrachyVision 6.0 (K992762)

Product Description:
VariSeed 7.1 is a computer based software application for planning and evaluating prostate brachytherapy procedures.

Hardware Platform and Operating System

The application runs on standard Intel PCs under Microsoft Window® 32-bit operating systems.

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Peripherals and Accessories

The application interfaces with video sources, printers, network sources, as well as DICOM and other image and data sources.

Software Features

1. *Image Acquisition/Import*: The ability to acquire patient data from which a plan or evaluation is constructed
2. *Structure Contouring*: The ability to define patient structures within the image space.
3. *Source Placement & Dosimetry*: The ability to plan source placement within the image space and to calculate the resulting dosimetry.
4. *2D and 3D visualization*: The ability to visualize the resulting dose profile and structure in 2D and 3D.
5. *Reporting*: The ability to produce hard and soft copy reports to facilitate the delivery of the plan, to document the plan and to document the post-procedure evaluation.
6. *Brachy Source Specification*: The ability for the expert user to modify the profile of seed source specifications and device specifications.
7. *Database functions*: The ability to manage the patient data in the application database including archiving, deleting and restoring data.
8. *Licensing*: The ability to license the system by application function and interface.
9. *Interface*: The ability to interface with other planning systems.

Application Development

The application was developed for 32-bit Microsoft Windows® operating system using Microsoft Visual C++.

Intended Use:

VariSeed 7.1 is a software application used for planning and evaluation of brachytherapy procedures.

Technological Characteristics:

The VariSeed 7.1 treatment planning system is substantially equivalent to the brachytherapy functions of the Varian Medical Systems, Inc. VariSeed 7.0 (K982821) and Varian Medical System, Inc. BrachyVision 6.0 (K992762) treatment planning systems.

The table below compares the feature sets of the three devices. The new software features for VariSeed 7.1 are in bold, all other VariSeed features are supported in a currently approved product.

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The intended use and indications for use of VariSeed 7.1 have been broadened to account for HDR image acquisition functionality. The intent of this functionality is more clearly stated below.

VariSeed 7.1 is substantially equivalent to the two predicate devices offering functionality for planning and evaluating brachytherapy procedures for the treatment of prostate cancer that can be modeled according to AAPM TG-43.

Significant functionality improvements to VariSeed 7.1 include anisotropy function and a utility for acquiring images and inputting pre-plan artifacts for high dose rate (HDR) brachytherapy planning. Each is available in the predicate BrachyVision device. With the addition of anisotropy function as a dose calculation method clinicians can have the option of representing dose distributions according to another model supported by the TG-43 standard. The HDR capture utility uses existing capabilities in the VariSeed 7.0 device to provide a simplified interface for acquiring ultrasound images and inputting pre-plan artifacts that can be exported according to the DICOM RT standard. The level of concern for VariSeed 7.1 is moderate. VariSeed 7.1 is not intended for diagnostic purposes nor will it control the delivery of the plan. Plan implementation will continue to be performed manually.

VariSeed 7.0 (Predicate)	**BrachyVision (Predicate)**	**VariSeed 7.1 (New)**
	Work Flows	
Off-line planning with or without ultrasound images	Off-line planning with or without ultrasound images	Off-line planning with or without ultrasound images
Real-time planning using images acquired from ultrasound	Real-time planning using images acquired from ultrasound	Real-time planning using images acquired from ultrasound
Nomogram planning	Nomogram planning	Nomogram planning
	HDR Image Acquisition utility	**HDR Image Acquisition utility-** ***The HDR capture utility uses existing capabilities in the VariSeed 7.0 device to provide a simplified interface for acquiring ultrasound images and inputting pre-plan artifacts that can be exported according to the DICOM RT standard.***
	Calculation	
AAPM TG-43 Support for Anisotropy Constant	AAPM TG-43 Support for Anisotropy Constant	AAPM TG-43 Support for Anisotropy Constant
AAPM TG-43 Support for Anistropy Factor	AAPM TG-43 Support for Anistropy Factor	AAPM TG-43 Support for Anistropy Factor
	AAPM TG-43 Support for Anisotropy Function	**AAPM TG-43 Support for Anisotropy Function-** ***With the addition of anisotropy function as a dose calculation method clinicians can have the option of representing dose distributions according to another***

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		model supported by the TG-43 standard.
Real-time calculation of isodoses and display over patient anatomy as isodose lines.	Real-time calculation of isodoses and display over patient anatomy as isodose lines.	Real-time calculation of isodoses and display over patient anatomy as isodose lines.
Automatic source decay	Automatic source decay	Automatic source decay
Industry Conformance		
Conforms to AAPM TG-43 – Dosimetry of interstitial brachytherapy sources	Conforms to AAPM TG-43 – Dosimetry of interstitial brachytherapy sources	Conforms to AAPM TG-43 – Dosimetry of interstitial brachytherapy sources
General		
Independent of the radiation delivery system	Independent of the radiation delivery system	Independent of the radiation delivery system
Hardcopy reports of all views	Hardcopy reports of all views	Hardcopy reports of all views
Planning support for all solid source delivery systems – line, seed, and seed train	Planning support for all solid source delivery systems – line, seed, and seed train	Planning support for all solid source delivery systems – line, seed, and seed train
User defined dose points	User defined dose points	User defined dose points
Manual structuring	Manual structuring	Manual structuring
Manual source localization	Manual source localization	Manual source localization
Window level tools	Window level tools	Window level tools
Multiple plan variations	Multiple plan variations	Multiple plan variations
Ultrasound import from DICOM	Ultrasound import from DICOM	Ultrasound import from DICOM
Included source management utilities	Included source management utilities	Included source management utilities
Included patient management utilities	Included patient management utilities	Included patient management utilities
Automated prostate contouring.	Automatic structure contouring	Automated prostate contouring.
Contour editing	Contour editing	Contour editing
Contour interpolation	Contour interpolation	Contour interpolation
Contour margining	Contour margining	Contour margining
Point and line landmarks.	Reference points and lines	Point and line landmarks.
Source location export	Plan export	Source location export
Volume editing	Volume editing	Volume editing
Image and structure data export to DICOM	Image and structure data export to DICOM	Image, structure, and plan data export to DICOM
Dosimetric quality alerts	Unacceptable dose values are flagged in the Plan Organizer.	Dosimetric quality alerts
Image set co-registration	Image set co-registration	Image set co-registration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Ms. Linda S. Nash
Corporate Director, Regulatory
Affairs and Quality Assurance
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K030534
Trade/Device Name: VariSeed 7.1
Regulation Number: 21 CFR §892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: February 14, 2003
Received: February 20, 2003

Dear Ms. Nash:

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 (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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Statement of Indications for Use

510(k) Number (if known): K030534

Device Name: VariSeed 7.1

Indications for use:

VariSeed 7.1 is a software application for planning and evaluating brachytherapy procedures for the treatment of prostate cancer that can be modeled according to AAPM TG-43. It facilitates pre-operative planning and post-operative evaluation as well as intra-operative planning and evaluation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR **Over-The-Counter Use** ____ (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030534