



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, Regulatory Affairs  
911 Hansen Way  
PALO ALTO CA 94304

May 8, 2015

Re: K150636  
Trade/Device Name: VariSeed 9.0  
Regulation Number: 21 CFR 892.5730  
Regulation Name: Radionuclide brachytherapy source  
Regulatory Class: II  
Product Code: KXK, MUJ  
Dated: March 9, 2015  
Received: March 11, 2015

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 yours,

 for

Robert Ochs, Ph.D.  
Acting 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): K150636

Device Name: VariSeed 9.0

Indications For Use:

VariSeed is indicated for use as a treatment planning software application used by medical professionals to plan, guide, optimize and document low-dose-rate brachytherapy procedures and for use as a biopsy procedure tracking software application used by medical professionals to plan, guide, and document biopsy procedures based on template guided needle insertion. VariSeed may be used on any patient considered suitable for this type of treatment and is intended to be used outside of the sterile field in an operating room environment or in a normal office environment.

Prescription Use    
 (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)

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Concurrence of Center for Devices and Radiological Health (CDRH)

PREMARKET NOTIFICATION

510(k) Summary

VariSeed 9.0

As required by 21 CFR 807.92

**Submitter's Name:** Varian Medical Systems  
3100 Hansen Way, m/s E110  
Palo Alto CA94304

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Date: 9th March 2015

**Proprietary Name:** VariSeed 9.0

**Classification Name:** system,planning,radiation therapy treatment  
21CFR892.5050, MUJ, Class II

**Common/Usual Name:** VariSeed,

**Predicate Devices:** VariSeed 7.1 (K030534)

**Device Description:** VariSeed 9.0 is a free-standing PC based treatment planning software product designed for preoperative and intraoperative planning of LDR implants, intraoperative tracking of the implant procedure, and postoperative evaluation of completed implants. VariSeed also provides tools for supporting intraoperative template guided biopsy and using those results to guide future treatment.

**Indications for Use:** VariSeed is indicated for use as a treatment planning software application used by medical professionals to plan, guide, optimize and document low-dose-rate brachytherapy procedures and for use as a biopsy procedure tracking software application used by medical professionals to plan, guide, and document biopsy procedures based on template guided needle insertion. VariSeed may be used on any patient considered suitable for this type of treatment and is intended to be used outside of the sterile field in an operating room environment or in a normal office environment.

**Changes in Technological Characteristics:**

The significant changes compared with the predicate are changes associated with and introducing (VariPath) which is designed to be used in the Operating Room as part of ultrasound guided structured biopsy procedures and with new features which make VariSeed usable as a general LDR treatment planning system.

The complete list of changes and their related requirements can be found in the document Tracing Changed/New Features to System Requirements in Section 18 of this submission.

**Device Comparison Table**

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PREDICATE DEVICE <b>VariSeed 7.1 – K030534</b>	<b>VariSeed 9.0</b>
<b>Intended Use</b>	VariSeed 7.1 is a software application used for planning and evaluation of brachytherapy procedures.	VariSeed is intended for use as a software application used by medical professionals to plan, guide, optimize, and document low dose rate brachytherapy and procedures based on template guided needle insertion
<b>Indications for Use</b>	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.	VariSeed is indicated for use as a treatment planning software application used by medical professionals to plan, guide, optimize and document low-dose-rate brachytherapy procedures and for use as a biopsy procedure tracking software application used by medical professionals to plan, guide, and document biopsy procedures based on template guided needle insertion. VariSeed may be used on any patient considered suitable for this type of treatment and is intended to be used outside of the sterile field in an operating room environment or in a normal office environment.
<b>Device Description</b>	VariSeed 7.1 is a computer based software application for planning and evaluating prostate brachytherapy procedures.	VariSeed 9.0 is a free-standing PC based treatment planning software product designed for preoperative and intraoperative planning of LDR implants, intraoperative tracking of the implant procedure, and postoperative evaluation of completed implants. VariSeed also provides tools for supporting intraoperative template guided biopsy and using those results to guide future treatment.
Off-line planning with or without ultrasound images	Yes	Yes
Real-time planning using images acquired from ultrasound	Yes	Yes
Nomogram planning	Yes	Yes
Pre-operative planning from live ultrasound	Yes	Yes
Pre-operative planning from digitizer	Yes	Yes
Pre-operative planning from imported images	Yes	Yes
Post-operative evaluation from imported images	Yes	Yes

Post-operative evaluation from digitizer	Yes	Yes
Intra-operative plan and evaluation from live ultrasound	Yes	Yes
Template Guided Biopsy	No	Yes
AAPM TG-43 Support for Anisotropy Constant	Yes	Yes
AAPM TG-43 Support for Anisotropy Factor	Yes	Yes
AAPM TG-43 Support for Anisotropy Function	Yes	Yes
Real-time calculation of isodoses and display over patient anatomy as isodose lines.	Yes	Yes
Automatic source decay	Yes	Yes
Conforms to AAPM TG-43 – Dosimetry of interstitial brachytherapy sources	Yes	Yes
Plan Approval	No	Yes
Image import various file formats	Yes	Yes
Reformat volume of image data to primary image volume	No	Yes
Import a DICOM RT dataset including biopsy data	No (images only)	Yes
Support angle or curved needles	No	Yes
Initializing a plan based on the contents of an existing plan.	No	Yes
Dose display on images as color wash	No	Yes
biopsy details reports	No	Yes
biopsy tracking workspace	No	Yes
biopsy visualization workspace	No	Yes
Export DICOM RT	Yes	Yes, including biopsy contents
Sector analysis for structures	No	Yes
Independent of the radiation delivery system	Yes	Yes
Hardcopy reports of all views	Yes	Yes

Planning support for all solid source delivery systems –seed, and seed train	Yes	Yes
User defined dose points	Yes	Yes
Manual contouring	Yes	Yes
Manual source localization	Yes	Yes
Window level tools	Yes	Yes
Multiple plan variations	Yes	Yes
Included source management utilities	Yes	Yes
Included patient management utilities	Yes	Yes
Automated prostate contouring.	Yes	Yes
Contour editing	Yes	Yes
Contour interpolation	Yes	Yes
Contour margining	Yes	Yes
Point and line landmarks.	Yes	Yes
Source location export	Yes	Yes
Volume editing	Yes	Yes
Image, structure, and plan data export to DICOM	Yes	Yes
Dosimetric quality alerts	Yes	Yes
Image set co-registration	Yes	Yes

### Non-clinical Testing

Verification and Validation were performed for all the new features and regression testing was performed against the existing features of VariSeed. System requirements created or affected by the changes can be traced to the test outcomes.

Standards applied during testing were:

1. IEC 62366(2007), Medical devices-- Application of usability engineering to medical devices-
2. IEC 62083(2009), Medical electrical equipment-Requirements for the safety of radiotherapy treatment planning systems
3. IEC 63204(2009), Medical Device Software-Software lifecycle processes

### **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 VariSeed 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 features of the current device is different to the predicate. Of these, the significant changes compared with the predicate are associated with extending the Indications for Use of VariSeed beyond the prostate to other treatment sites and introducing (VariPath) which is designed to be used in the Operating Room as part of ultrasound guided structured biopsy procedures. The use of the predicate and the new device, for both of the indications for use, involves the planning, guiding, and documenting the procedure.

Referring to the 510(k) Decision-Making Flowchart in “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” Guidance Notes:

1. The predicate (VariSeed 7.1) is a legally marketed device. (K030534)
2. The device and its predicate have the same intended use. (Note: wording of Intended Use statement has been updated to include more detail on use).
3. The device and its predicate have the same technological characteristics.

Changes in VariSeed 9.0, compared to the predicate, can be traced to their related System Requirements using the document “Tracing Changed or New Features to System Requirements.” The System Requirements can then be traced to the test procedures using the Requirements to Procedures Trace Matrix. The Test Reports show the test, the expected and observed results and whether the test is a pass or fail.

For all testing, including testing of the changes, there were no DRs (discrepancy reports) remaining which had a priority of Safety Intolerable or Customer Intolerable.

Varian considers the changes to be enhancements of the predicate. There are no changes in the principle of operation of the software. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes that VariSeed 9.0 is substantially equivalent to the predicate.