Varian Medical Systems
% Lynn Allman
Director, Regulatory Affairs
3100 Hansen Way
M/s E-110
PALO ALTO CA 94304

September 8, 2023

Re: K232400
Trade/Device Name: VariSeed (v10)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ, KXK
Dated: August 8, 2023
Received: August 10, 2023

Dear Lynn Allman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232400

Device Name
Variseed 10.0

Indications for Use *(Describe)*
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.

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification 510(k) Summary

K232400

The following information is provided according to 21 CFR 807.92.

Submitter:	Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304	Contact Name: Lynn Allman E-mail: submissions.support@varian.com Date Prepared: Aug 8, 2023

Trade/ Proprietary Names:	VariSeed v10.0	
	Common/Usual Name: Brachytherapy treatment planning software **Classification Name**: System, planning, radiation therapy treatment, 21 CFR §892.5050 **Product Code:** MUJ **Regulatory Class:** Class II	**Predicate Device:** VariSeed v9.0 (K150636)

Device Description:	VariSeed 10 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.

Intended/ Indications for Use Statement:	**Intended Use**	**Indications for Use**
	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.	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.

The purpose of this submission is to provide details on how the modified **VariSeed** v10.0 is similar to Varian's **VariSeed** v9.0 (K150636) for which we are claiming substantial equivalence.

The subject device Indications for Use is the same as the predicate device and the Intended Use is the same as the predicate device.

Comparison of Technological Characteristics with the Predicate Device

At a high level, the subject and predicate devices are based on the following similar elements:

- Design, technological characteristics, operation and use as the Predicate device

Significant Difference

The significant differences (based on "Deciding When to Submit a 510(k) for a Software Change to an Existing Device. (October 2017)") compared to the predicate device are:

- Provide support for PET images as secondary image volumes.
- Inclusion of MR Images in existing image import-based workflow for VariPath.

Performance Data

Verification and validation were conducted according to QSR §820.30 and ISO 13485:2016 design control requirements. Submission documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s.

Verification testing was performed to demonstrate that the performance and functionality of the **VariSeed v10** treatment planning software meets the design input requirements. Validation testing was performed on production equivalent devices, under clinically representative conditions and by qualified personnel. International standards were incorporated into the device design and development.

No clinical tests have been included in this pre-market submission.

Standards Conformance

The subject device conforms in whole or in part with the following standards:

- ISO 14971:2019
- IEC 62083:2009
- IEC 62366-1:2015 +A1:2020
- ISO 20417:2021
- ISO 15223-1:2021
- IEC 62304-1:2006 +A1:2015
- IEC 82304-1:2016

The subject device also complies with the following non-FDA recognized standard:

- ISO 13485:2016

Conclusion

The non-clinical data for the **VariSeed** v10 treatment planning software supports the safety of the device compared to the predicate and the verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Varian considers the **VariSeed** v10 treatment planning software to be as safe and effective as the predicate, and therefore substantially equivalent to the predicate device.