April 25, 2025

Varian Medical Systems
Lynn Allman
Senior Director of Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K250289
Trade/Device Name: Intracavitary/Interstitial System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: January 31, 2025
Received: January 31, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250289

Device Name

Intracavitary/Interstitial System

Indications for Use *(Describe)*

The Intracavitary/ Interstitial System is intended for cancer treatment of the uterus, cervix, and vagina using HDR or PDR brachytherapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

varian
A Siemens Healthineers Company

Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Intracavitary/Interstitial System

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Lynn, Allman, PhD., Senior Director Regulatory Affairs
Phone: (650) 424-5369
E-mail: submissions.support@varian.com
Date Prepared: January 31, 2025

II. Device Information

Proprietary Name: Intracavitary/Interstitial System
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Geneva (K201272)

IV. Device Description

The Intracavitary/Interstitial System is intended for cancer treatment of the uterus, cervix, and vagina using HDR or PDR brachytherapy.

The Intracavitary/Interstitial System is a device with two (2), hollow, open-ended catheters which connect to applicator sets with ovoids, ring caps or templates on the distal end.

The guide tubes extend outside of the patient. An interstitial needle is guided through the guide tube from outside the patient to an interstitial hole in the applicator. The proximal end of the guide tube contains a fixation mechanism for fixing the needle insertion depth between needle insertion and removal of the implant.

The Intracavitary/Interstitial System is intended to be used with the following required accessories: Plastic Needles (K120341) and Leak Stop Channel Markers (K152018).

V. Intended Use

The Intracavitary/Interstitial System is intended for cancer treatment of the uterus, cervix, and vagina using HDR or PDR brachytherapy.

VI. Indications for Use

The Intracavitary/Interstitial System is indicated for use for cancer treatment of the uterus, cervix, and vagina using HDR or PDR brachytherapy.

VII. Comparison of Technological Characteristics with the Predicate Device

The subject device and predicate device are indicated for intracavitary and interstitial brachytherapy for treatment of cancer.

- The subject device is a guide tube which is an accessory to be used with a compatible applicator for interstitial brachytherapy. The predicate device is a tandem and ovoid type applicator with compatible interstitial needles, which includes guiding tubes as an optional item for interstitial brachytherapy.
- The general design and purpose of the subject device guide tubes and the predicate device guiding tubes are similar.
- Both devices are MR Safe and made of biocompatible material.
- Both devices are used in the hospital by qualified physicians

VIII. Summary of Performance Testing (Non-Clinical Testing)

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing:
The compatibility of the skin-contact component material in the finished product meets the biocompatibility requirements. The Biological Evaluation Tests are in compliance with the standards of ISO 10993-1 and its applicable parts, "Biological Evaluation of Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process". Biocompatibility testing conducted included: Cytotoxicity, Irritation, Delayed Type Hypersensitivity, Material Mediated Pyrogen, and Acute Systemic Toxicity

Cleaning, Disinfection and Sterilization Testing:
Cleaning, disinfection and sterilization testing was conducted to demonstrate the device components may be sterilized effectively (as appropriate) and the device can be used and sterilized for the specified number of times.

Human factors validation study was conducted according to the standard IEC 62366 to verify that the device performs well as intended for the intended users, uses, and use environments.

Mechanical and Acoustic Testing:
Intracavitary/Interstitial System Applicator Set has undergone formal design verification and design validation testing. Design verification and design validation testing demonstrates that the device performs as intended.

Design verification and design validation testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, and ISO 14971 Risk Management Standard.

Magnetic Resonance Testing (MR):
MR Compatibility testing was completed, and documentation was provided to FDA in support of the substantial equivalence determination. The Intracavitary/Interstitial System is MR Safe and complies with the following MR standards:

ASTM F2052-21: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2213-17: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ASTM F2182-19: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

ASTM F2503-23: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

ASTM F2119-24: Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Electromagnetic Compatibility (EMC) Testing:

The electromagnetic compatibility of the Intracavitary/Interstitial System was assessed by testing the device to the requirements of IEC 60601-1 and IEC 60601-2-17. The results of the testing demonstrate that the subject device is compatible in an electromagnetic setting.

Use of Consensus Standards:
The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

Standard Number	Standard Title
ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
ISO 17665:2024	Sterilization of health care products –Moist heat – Requirements for the development, validation and routine control of a sterilization process for medical devices

Standard Number	Standard Title
ISO 10993-11:2018	Biological evaluation of medical devices –Part 11: Tests for systemic toxicity
ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020/Amd 1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23:2021	Biological evaluation of medical devices –Part 23: Tests for irritation
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2182-19	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance
ASTM F2052-21	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2503-23	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

IX. Determination of Substantial Equivalence to the Predicate

Feature and/or Specification	Predicate Device: Geneva (K201272)	Subject Device: Intracavitary/Interstitial System	Comparison
Intended Use	-	The Intracavitary/ Interstitial System is intended for cancer treatment of the uterus, cervix, and vagina using HDR or PDR brachytherapy.	**Similar** Both devices are indicated for intracavitary and interstitial brachytherapy for treatment of cancer. The subject device is used an accessory with applicator sets which are indicated for HDR and PDR brachytherapy
Indications for Use	The device is intended for intracavitary brachytherapy for cancer treatment of the cervix and the endometrium. Optional needles can be placed for interstitial brachytherapy.	The Intracavitary/Interstitial System is indicated for use for cancer treatment of the uterus, cervix, and vagina using HDR or PDR brachytherapy	
Design	<u>Applicator Parts:</u> Ovoid Tube	<u>Guide tube for Ø 2.0 mm needles</u> Length: 193mm Inner Diameter: 3.6mm Outer Diameter: 4.5mm	**Similar** The subject device is a guide tube which is an accessory to be used

Feature and/or Specification	Predicate Device: Geneva (K201272)	Subject Device: Intracavitary/Interstitial System	Comparison
	Intrauterine Tube: • Length: 0, and 30 to 80 mm • Angle: 15°, 30°, 45° Interstitial Tube Interstitial Ovoid Pair • Length: 15mm, 20mm, 25mm, 30mm, 35mm, 40mm Rectal Retractor: • Width: 20, 30, and 40 mm Spreading Clip Tubes locking clip <u>Optional Items for Interstitial Use</u> Guiding Tubes ProGuide Needle Sets		with an applicator for interstitial brachytherapy. This is similar to the predicate device which includes guiding tubes as an optional item for interstitial brachytherapy.
Technological Description	The Geneva is a gynecological applicator for intracavitary brachytherapy with the option for interstitial brachytherapy treatment. It can be used for the treatment of the cervix and endometrium. The applicator consists of tubes and ovoids**,** guiding the radioactive source of the afterloader to the target volume. Compatible components can be combined to reach a wide range of target areas. The unique interstitial tube (I-tube) also enables clinicians to reach cancerous tissue around the vaginal cuff following hysterectomy. With ProGuide needles and guiding tube, the I-tube enhances accurate and reproducible dose distributions in hysterectomy patients and	The IIS consists of the guide tubes which are hollow, open-ended catheters which connect to applicator sets with ovoids, ring caps or templates on the distal end. The guide tubes extend outside of the patient. An interstitial needle is guided through the guide tube from outside the patient to an interstitial hole in the applicator. The proximal end of the guide tube contains a fixation mechanism for fixing the needle insertion depth between needle insertion and removal of the implant.	**Similar** Both devices include a guide tube to support interstitial brachytherapy treatment. Compatible interstitial needles are guided through the guide tube to the needle holes in compatible applicator components. The predicate device is a tandem and ovoid type applicator with compatible interstitial needles. The subject device is a guide tube that is compatible with applicators such as the CT/MR Tandem and Ovoid Set (Parallel 510(k) submission).

Feature and/or Specification	Predicate Device: Geneva (K201272)	Subject Device: Intracavitary/Interstitial System	Comparison
	eliminates the need for free-hand needle placement.		
Material	Applicator is entirely made out of non-metallic materials like PPSU & reinforced glass fiber	Guide Tube: FEP / PEEK	Both devices are made of commonly used, biocompatible materials
Anatomical Sites	Cervix and endometrium	Uterus, cervix, and vagina	Both devices are indicated for anatomical sites for intracavitary and interstitial brachytherapy for treatment of cancer. The subject device is used as an accessory to compatible applicators. Compatible applicators such as Titanium Flexible Geometry FSD Applicator Set (K243939 – In 510(k) Review) and CT/MR Tandem and Ovoid Set (Parallel 510(k) submission) include indications for the uterus, cervix, and vagina, which is similar to the subject device.
MR Environment	MR Safe	MR Safe	**Similar** The predicate and subject device are both MR Safe
Use Environment	Hospital by qualified physicians	Radiation therapy or radiation oncology department in a hospital environment.	**Similar** Both are used in a hospital environment by qualified physicians

Based on the comparisons outlined above, Varian believes the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness compared to the predicate.

The results of verification and validation as well as conformance to relevant safety standards demonstrate that the device meets the safety and performance criteria.

Varian considers the Intracavitary/Interstitial System to be as safe and effective as the predicate and therefore substantially equivalent to the predicate device.