Varian Medical Systems
Lynn Allman
Sr. Director Regulatory Affairs
3100 Hansen Way
Palo Alto, California 64304

November 26, 2024

Re: K242961
Trade/Device Name: Intraluminal Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: September 25, 2024
Received: September 25, 2024

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)*

K242961

Device Name

Intraluminal Applicator Set

Indications for Use *(Describe)*

The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endobronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR 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.

K242961

Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Intraluminal Applicator Set

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: September 24, 2024

II. Device Information

Proprietary Name: Intraluminal Applicator Set
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Intraluminal Applicator Set (K151022)

IV. Device Description

The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endobronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.

The Intraluminal Applicator Set acts to guide the radioactive source to the correct location or locations for treatment.

Key performance characteristics are as follows:

- Suitable for treating body sites allowing insertion of a catheter.
- CT compatible.

- MR Compatibility: Safe.
- Fits a 2 mm diameter bronchoscope biopsy channel allowing for easy insertion.
- Elastomer construction provides increased flexibility for easy placement and luminal rigidity to avoid kinks.
- Nylon monofil adds luminal stability during catheter insertion and manipulation.
- Comes with 2.8 mm spacing tubes, which minimize surface dose.
- Spacing tubes enable secure placement during treatment.
- The bronchial catheter and monofil are supplied sterile, and for single use.
- The guide tubes, the bronchial catheter, the bite protector, and the tube catheters are intended for continuous use for less than 24 hours of contact with patients.

V. Intended Use

The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endobronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject Device to Predicate Device

Feature and/or Specification of new/modified device	Predicate Device: Intraluminal Applicator Set (K151022)	Subject Device: Intraluminal Applicator Set	Comparison
Intended use	The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.	The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endobronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.	No change

Feature and/or Specification of new/modified device	Predicate Device: Intraluminal Applicator Set (K151022)	Subject Device: Intraluminal Applicator Set	Comparison
Indications for Use	The Intraluminal Applicator Set is indicated for use for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.	The Intraluminal Applicator Set is indicated for use for intraluminal brachytherapy treatments including endobronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.	No change
Compatible Afterloader	GammaMedplus plus	GammaMedplus Afterloader Series BRAVOS Afterloader System (K221797)	Added compatibility to the BRAVOS Afterloader System for completeness
Design	**Components:**	**Components:**	
	Bronchial catheter 5 Fr. (Ø 1.67mm) (material PA)	Bronchial catheter 5 Fr. (Ø 1.67mm) (material PA)	No change
	Guide tube Ø 2.8mm, length 900mm (material FEP)	Guide tube Ø 2.8mm, length 900mm (material FEP)	No change
	Monofil, Ø 0.8 mm, for bronchial catheter, sterile (material PA)	Monofil, Ø 0.8 mm, for bronchial catheter, sterile (material PA)	No change

Feature and/or Specification of new/modified device	Predicate Device: Intraluminal Applicator Set (K151022)	Subject Device: Intraluminal Applicator Set	Comparison
	Bite protector for intraluminal applicators (material PPSU)	Bite protector for intraluminal applicators (material PPSU)	No change
	Components Required for Afterloaders:	**Components Required for Afterloaders:**	
	3rd party component "GM11004210 guide wire, 0.032" x 2600 mm, sterile"	No longer included	The feature and use of the Intraluminal Applicator does not depend on the guide wire. The guide wire is used (if needed) to place the Intraluminal Applicator in the patient's body. If the customers need a guide wire they can purchase a suitable guide wire locally
	Clamping adapter for 5 Fr bronchial catheter, GammaMedplus (material Stainless Steel)	Clamping adapter for 5 Fr bronchial catheter, GammaMedplus (material Stainless Steel)	No change
	No clamping adapter for BRAVOS Afterloader system	Clamping adapter for 5 Fr bronchial catheter, BRAVOS (material Stainless Steel)	Added component to support compatibility with the BRAVOS Afterloader System (K221797)

Feature and/or Specification of new/modified device	Predicate Device: Intraluminal Applicator Set (K151022)	Subject Device: Intraluminal Applicator Set	Comparison
	Optional Components and Accessories:	**Optional Components and Accessories:**	
	Guide tube, Ø 4.5 mm, length 700 mm (material FEP)	Guide tube, Ø 4.5 mm, length 700 mm (material FEP)	No change
	Tube catheter, Ø 2.8 mm, GammaMedplus (material FEP/Stainless Steel)	Tube catheter, Ø 2.8 mm, GammaMedplus (material FEP/Stainless Steel)	No change
	No tube catheter,	Tube catheter (material FEP/Stainless Steel)	Added tube catheter to support use with BRAVOS Afterloader System
Tube Catheter	Tube catheter included as optional accessory	Tube catheter included as optional accessory	No change
Materials	PA (Polyamide) FEP (Fluorinated Ethylene Propylene) Stainless Steel PPSU (Polyphenylsulfone)	PA (Polyamide) FEP (Fluorinated Ethylene Propylene) Stainless Steel PPSU (Polyphenylsulfone)	No Change
Packing	Individual	Individual and Pack of 5 and 10	Added packs of 5 and 10 to expand product offerings

Feature and/or Specification of new/modified device	Predicate Device: Intraluminal Applicator Set (K151022)	Subject Device: Intraluminal Applicator Set	Comparison
Sterility (Bronchial catheter and Monofil)	Supplied sterile –single use only	Supplied sterile –single use only	No change
Biocompatibility Contact Duration	Bronchial Catheter: 24hr to 30 days Guide Tube: Up to 24h Tube Catheter: 24hr to 30 days	Intraluminal Applicator Set: Up to 24 Hours	The revised contact time was chosen based on typical clinical use of the product and the biocompatibility data included as part of this submission.
Sterilization method (Bronchial catheter and Monofil)	Gamma sterilization (shelf-life 5 years)	EtO sterilization (shelf-life 2 years)	Updated sterilization method to EtO for consistency with other, Varian applicator sets
Sterilization method (Guide Tubes)	Steam sterilization –single use only	Steam sterilization –single use only	No change
Sterilization method (Tube Catheter)	High level disinfection up to 20 times	High level disinfection up to 20 times	No change
Biocompatibility	Fully biocompatible	Fully biocompatible	No change
Anatomical sites	Endo-bronchial treatments, esophagus (using a guide tube), and the bile duct	Endo-bronchial treatments, esophagus (using a guide tube), and the bile duct	No change

Feature and/or Specification of new/modified device	Predicate Device: Intraluminal Applicator Set (K151022)	Subject Device: Intraluminal Applicator Set	Comparison
Human factors	Controlled through Varian afterloaders	Controlled through Varian afterloaders	No change
Compatibility with the environment and other devices	CT compatible and MR Safe (MR Safe components as listed in Instructions for Use are used)	CT compatible and MR Safe (MR Safe components as listed in Instructions for Use are used)	No change
Where used	Brachytherapy treatment room	Brachytherapy treatment room	No change

VII. 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:
Intraluminal Applicator Set 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 Intraluminal Applicator Set is MR Safe and complies with the following MR standard:

- ASTM F2503-23 (2023 ED): Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Electromagnetic Compatibility (EMC) Testing:

The electromagnetic compatibility of the Intraluminal Applicator Set 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.

ANSI/AAMI/ISO 14971:2019	Medical devices – Applications of risk management to medical devices
EN ISO 15223-1:2021	Medical devices – Symbols to be used with the information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417: 2021	Information supplied by the manufacturer of medical devices
IEC 62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
ANSI/AAMI ST98:2022	Cleaning Validation of health care products –cleaning process for medical devices
ANSI / AAMI ST79:2017(R)2022	Comprehensive guide to steam sterilization and sterility assurance in health care facilities

ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices –Part 1: Critical and semi-critical medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices –Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISTA 3A (2018)	General Simulation Performance Tests for packaged-products weighing 150 lb. (70 kg) or less (standard, small, flat or elongated)
EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices –Part 12: Sample preparation and reference materials
ISO 10993-18:2020/ AMD 1:2022	Biological evaluation of medical devices -- Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation
IEC 60601-2-17:2013	Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment
ASTM F2503 –23	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ASTM D4332-22	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
EN ISO 10993-2:2022	Biological evaluation of medical devices. –Part 2: Animal welfare requirements
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

VIII. Determination of Substantial Equivalence to the Predicate

The Intraluminal Applicator Set was previously marketed under K151022. There are no changes in the design or principle of operation of the devices.

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 Intraluminal Applicator Set to be as safe and effective as the predicate and therefore substantially equivalent to the predicate device.