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

October 29, 2024

Re: K241965
Trade/Device Name: Catheter Surface Flap Applicator Set (GM11011830)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: October 2, 2024
Received: October 2, 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)*

K241965

Device Name

Catheter Surface Flap Applicator Set (GM11011830)

Indications for Use *(Describe)*

The Catheter Surface Flap Applicator Set is intended for use for skin cancer treatment 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.

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Premarket Notification – K241965 510(k) Summary

Traditional 510(k) Submission for Catheter Surface Flap 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: July 3, 2024

II. Device Information

Proprietary Name: Catheter Surface Flap Applicator Set (GM11011830)
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

GammaMed*plus* High Dose Rate Remote Afterloading System (K983436)

IV. Device Description

The Catheter Surface Flap Applicator Set qualifies as a medical device as it is used on human beings for the purpose of cancer treatment.

The key performance characteristics of this applicator set are as follows:

- Surface applicator intended for the treatment of skin cancers.
- A 10mm thick flap allowing for up to 38 channels spaced at 5 mm allows for a large uniform treatment.
- Hollow pattern design and semi translucent material provides good visibility of the treatment area.
- The material high flexibility allows the applicator to conform closely to complex patient anatomies such as when treating nose or ear lesions.
- Silicone material gives excellent biocompatibility and durability.
- Single patient multiple use.
- The Catheter Surface Flap is MR and CT compatible.
- Patient-contacting parts constructed of silicone and Polyvinylchloride; suitably for patient contact for a period up to 24 hours.

The Catheter Surface Flap Applicator Set is an applicator for Brachytherapy. Brachytherapy is a form of radiotherapy using Gamma rays from a radioactive source placed at locations close to or within a tumor or other treatment area to a predefined treatment plan. The treatment plan defines the positions and

times for the source to ensure the correct dose for the treatment area. The applicator acts to guide the radioactive source to the correct location or locations for treatment.

The fixation buttons are used for locking the mould probes in place after insertion in the catheter surface flap. Some of these are supplied in the fixation button kits but they are also available to be purchased separately as spares. As spares, they are packed in sterile pouches, with 10 pieces per pouch and sold as pack of 10 pouches respectively.

V. Indications for Use

The Catheter Surface Flap Applicator Set is intended for use for skin cancer treatment using HDR or PDR brachytherapy.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject Device to Predicate Device

Feature and/or Specification	Predicate Device: GammaMed plus High Dose Rate Remote Afterloading System (K983436)	Subject Device: Catheter Surface Flap Applicator Set	Comparison
Intended Use	The intended use of the GammaMed Plus transportable high-dose-rate remotedly controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intralumenal and intraoperative irradiation.	The Catheter Surface Flap Applicator Set is intended for use for skin cancer treatment using HDR or PDR brachytherapy.	Changed - Device will now be registered as an individual product (in the last 510(k) the Catheter Surface Flap was an accessory of K983436). Accordingly the intended use statement is updated to be more specific to the applicator set, rather than the Afterloader with which it is used. This applicator's action is exactly the same for High Dose Radiation (HDR) treatment and Pulse Dose Rate (PDR) treatment. The only difference with the HDR and PDR treatments are fractions delivered and some activity level. Both treatments deliver the source from the afterloader, through the source guide tube to the catheter surface flap and to the patient treatment location.
Indications for Use	The intended use of the GammaMed Plus	The Catheter Surface Flap Applicator Set is intended	Changed - Device will now be registered as an individual

	transportable high-dose-rate remotedly controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intralumenal and intraoperative irradiation.	for use for skin cancer treatment using HDR or PDR brachytherapy.	product (in the previous 510(k) the Catheter Surface Flap was an accessory of K983436).
Compatible Afterloader	GammaMed*plus* Series VariSource Series (200 and iX)	GammaMed*plus* Series BRAVOS Afterloader System	Changed – removal of VariSource and addition of BRAVOS
The comparison below compares the principal components of the subject device to the relevant accessories of the K983436 predicate device. Refer to bolded text for the differences between components that are the subject of this submission. Leak Stop Channel Marker Set and Cleaning Caps are covered in K152018. Mould probe with mandrin is covered in K241764.			
Design	Catheter Flap: 200 mm x 290 mm x 10 mm 40 channels 2 mm channel diameter 5 mm distance between each channel Mould probe with mandrin: ø 1.8 mm, 320 mm length Fixation Button, radiopaque, pack of 100, non-sterile: 3 mm length Outer diameter 4.2 mm Inner diameter 1.2 mm	Catheter Flap: 200 mm x 290 mm x 10 mm **38 channels** 2 mm channel diameter 5 mm distance between each channel **Hollow Pattern Design** Mould probe MR Safe with mandrin: ø 1.8 mm, 320 mm length Fixation Button, pack of 10x10, **sterile**: 3 mm length Outer diameter 4.2 mm Inner diameter **1.4 mm** Leak Stop Channel Marker Set: 2 mm length Outer diameter 10 mm Inner diameter 1 mm Cleaning Caps: 11 mm length Outer diameter 5.07 mm Inner diameter 2.03 mm	Changed – Now includes updated Catheter Flap component. Updated Mould Probe (now MR Safe) covered in K241764. Now includes sterile fixation buttons as components which differ in shore hardness and inner diameter. Now includes Leak Stop Channel Marker Set and Cleaning Caps as components of the set (separately cleared K152018).
Materials	Catheter Flap: Silicone (ALPA-SIL CLASSIC Komponente A+B)	Catheter Surface Flap: Silicone (**75% Sorta Clear 18 and 25% of ECOflex Gel**)	Changed – The Flap material is changed from ALPA-SIL CLASSIC Komponente A+B to a silicone compound of 75%

	Mould probe: PA, Titanium Mandrin: Stainless Steel Fixation Button: PVC	Mould probe: PA, **PEEK** Mandrin: Stainless Steel Fixation Button: PVC Leak Stop Channel Markers: Silicone Cleaning caps: Silicone	Sorta Clear 18 and 25% of ECOflex Gel in order to have a biocompatible applicator.
Environment	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".

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:
Catheter Surface Flap 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.

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

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

Catheter Surface Flap Applicator Set was previously sold as an accessory for the GammaMed*plus* High Dose Rate Remote Afterloading System (K983436). 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. 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 Catheter Surface Flap Applicator Set to be substantially equivalent to the predicate device.