March 3, 2025

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

Re: K243939
Trade/Device Name: Titanium Flexible Geometry FSD Applicator Set (GM11013400)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: December 19, 2024
Received: December 20, 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)*

K243939

Device Name

Titanium Flexible Geometry FSD Applicator Set (GM11013400)

Indications for Use *(Describe)*

The Titanium Flexible Geometry FSD Applicator Set with the optional interstitial ovoids is intended for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina, with intracavitary or with a combination of intracavitary and interstitial 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.

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

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K243939

Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Titanium Flexible Geometry FSD 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

II. Device Information

Proprietary Name: Titanium Flexible Geometry FSD Applicator Set
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Titanium Fletcher-Style Applicator Set Defined Geometry (K241853)

IV. Device Description

The Titanium Flexible Geometry FSD Applicator Set with the optional interstitial ovoids is intended for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina, with intracavitary or with a combination of intracavitary and interstitial HDR brachytherapy.

The device does not contain or consist of software/firmware. The device does not contain any biologics or drug components. The device has patient-contacting materials. The device is designed for repeated use. No parts of the system are provided sterile. The device can be steam sterilized with common parameters using pre-vacuum sterilization.

The intended patient population includes adult female patients whose cancer can be treated using HDR brachytherapy, as determined by the prescribing physician. The subject device is intended to be used in a healthcare or treatment facility by trained and qualified personnel.

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

- The ability to customize the relative depth of the tandem and ovoids, as well as adapt to different anatomies with three tandem angles (15°, 30°, 45°) and a movable cervical stop.
- 3.5 mm diameter intrauterine tandems allow for easy insertion into the cervical channel helping provide maximum patient comfort.
- The tandems and the pivot assembly are made from strong, lightweight titanium.
- Four different ovoid sizes to allow for varying anatomy.

- Channel marking on the intrauterine tandems and colpostat tandems for easy identification.
- Ability to image the patient using CT imaging.
- Ability to image the patient using MR imaging.
- Optional interstitial ovoids for more complex cases with guide tubes to allow for the needles to be preloaded outside of the patient and locked into place.
- Compatible with cervical sleeves to allow easy multiple fraction applications and help provide maximum patient comfort and eliminate the risk of perforation.
- Can be manually or machine cleaned, disinfected and steam sterilizable.
- Can be securely connected to the BRAVOS Afterloader System and GammaMedeplus iX series afterloader.
- Suitable for patient contact for a period of less than 30 days

V. Intended Use

The Titanium Flexible Geometry FSD Applicator Set with the optional interstitial ovoids is intended for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina, with intracavitary or with a combination of intracavitary and interstitial 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 DEVICE	Predicate Device: GM11006200 Titanium Fletcher-Style Applicator Set Defined Geometry (K241853)	Subject Device: GM11013400 Titanium Flexible Geometry FSD Applicator Set	Comparison
Intended use	The Titanium Fletcher-style Applicator Set Defined Geometry is intended for use for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina when performing HDR or PDR brachytherapy.	The Titanium Flexible Geometry FSD Applicator Set with the optional interstitial ovoids is intended for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina, with intracavitary or with a combination of intracavitary and interstitial HDR brachytherapy.	Similar, as both devices are intended for brachytherapy cancer treatment in the same anatomical areas. The subject device is not indicated for use with PDR brachytherapy.
Indications for Use	The Titanium Fletcher-style Applicator Set Defined Geometry is indicated for use for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina using HDR or PDR brachytherapy.	The Titanium Flexible Geometry FSD Applicator Set with the optional interstitial ovoids is intended for cancer treatment of the uterus, cervix, paracervix, endometrium and vagina, with intracavitary or with a combination of intracavitary and interstitial HDR brachytherapy.	Similar, as both devices are intended for brachytherapy cancer treatment in the same anatomical areas. The subject device is not indicated for use with PDR brachytherapy.
Device Classification	Class II, JAQ	Class II, JAQ	Same

FEATURE AND/OR SPECIFICATION OF NEW DEVICE	Predicate Device: GM11006200 Titanium Fletcher-Style Applicator Set Defined Geometry (K241853)	Subject Device: GM11013400 Titanium Flexible Geometry FSD Applicator Set	Comparison
Intended Patient Population	Adult female patients for which brachytherapy is determined to be an appropriate treatment by a prescribing physician	Adult female patients for which brachytherapy is determined to be an appropriate treatment by a prescribing physician	Same
Compatible Afterloader	GammaMed*plus* iX Afterloader Series BRAVOS Afterloader System VariSource Afterloader Series	GammaMed*plus* iX Afterloader Series BRAVOS Afterloader System	Similar, the subject device is not indicated for use with the VariSource afterloader series
Performance Characteristics	Device is made of biocompatible, sturdy, and lightweight components, which are marked for identification. Users can adjust components of the device and select from a variety of sizing for a range of anatomical sizes.	Device is made of biocompatible, sturdy, and lightweight components, which are marked for identification. Users can adjust components of device and select from a variety of sizing for a range of anatomical sizes.	Similar, there are differences in the design and optional accessories as detailed in Components and Design (& Optional Accessories).
Components and Design (& Optional Accessories)	Rigid design / defined geometry Pair of titanium colpostat probes (left and right): Titanium intrauterine probe with cervical stop 30°, Length: 40mm, 60mm, 80mm (optional 30mm, 50mm, 70mm) Diameter: 3mm Ovoids and mini-ovoids: Dimensions: 16, 20, 25, 30 mm Titanium central clamping mechanism Allen Key Cleaning Caps *Optional Components:* *Fixation for 3-channel applicators* *Titanium rectal retractor*	**Adjustable design / flexible geometry** Pair of titanium colpostat tandems (left and right): Titanium intrauterine tandems with cervical stop with **15°**, 30° and **45° curved**; Length: **Adjustable** Diameter: **3.5mm** Ovoids and mini-ovoids: Dimensions: 16, 20, 25 and 30mm; Titanium Tandem Pivot Assembly, Locking Nut, Cervical Stop; Cleaning Caps *Optional Components:* *Ovoid/cervical stop set screw* *Interstitial ovoids with fixation for guide tubes*	Similar, the primary difference is in the type of orientation angles available and adjustable design of the subject device. Both sets provide applicators for brachytherapy treatment for the same anatomical region.

FEATURE AND/OR SPECIFICATION OF NEW DEVICE	Predicate Device: GM11006200 Titanium Fletcher-Style Applicator Set Defined Geometry (K241853)	Subject Device: GM11013400 Titanium Flexible Geometry FSD Applicator Set	Comparison
	Needle collector *Headless screw Titanium* *Central fixation screw for intrauterine probe* *Fixation screws for colpostat probe* *Smit cervical sleeves: 30mm – 80mm*		
Materials	PEEK, PPSU, Titanium	PEEK, Titanium	Similar, the subject device uses no novel or different materials than those used in the predicate.
Packing	Individual	Individual	Same
Sterility	Delivered in non-sterile condition. To be sterilized at customer site. Number of sterilization cycle: 250 times & 500 times	Delivered in non-sterile condition. To be sterilized at customer site. Number of sterilization cycles: 250 times & 500 times	Same
Sterilization method	Manual and machine cleaning Manual and machine disinfection Steam sterilization	Manual and machine cleaning Manual and machine disinfection Steam sterilization	Same
Biocompatibility	Fully biocompatible	Fully biocompatible	Same
Anatomical sites	Uterus, cervix, paracervix, endometrium and vagina	Uterus, cervix, paracervix, endometrium and vagina	Same
Compatibility with the environment and other devices	CT compatible MR conditional	CT compatible MR conditional	Same
Where used	Brachytherapy treatment room	Brachytherapy treatment room	Same

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".

Magnetic Resonance Testing (MR):
MR Compatibility testing was completed, and documentation was provided to FDA in support of the substantial equivalence determination. The subject device is MR Conditional 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
- ASTM F2182-19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
- 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 F2119-07 (2013): Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

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.

A 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:
The subject device 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's safety and efficacy.

Standard/ CS	Standard/ CS Title
EN ISO 13485:2016	Quality management systems. Requirements for regulatory purposes
EN ISO 14971:2019+All:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN 62366-1:2015+AI:2020	Application of Usability Engineering to Medical Devices
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 17664-1:2021	Processing of health care products-Information to be provided by the medical device manufacturer for the processing of 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
EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-2:2022	Biological evaluation of medical devices. - Part 2: Animal welfare requirements
EN ISO 10993-5:2009	Biological evaluation of medical devices - part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	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
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2020	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
EN 60601-1:2006/AI:2013	Medical Electrical Equipment Part 1- General Requirements For Safety and essential performance
EN 60601-2-17:2015	Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment

VIII. Determination of Substantial Equivalence to the Predicate

Subject Device: Titanium Flexible Geometry FSD Applicator Set
Predicate device: Titanium Fletcher-Style Applicator Set Defined Geometry (K241853)

1. Is the predicate device legally marketed?

510(k) Summary
Traditional 510(k) Application
Titanium Flexible Geometry FSD Applicator Set

Yes, the predicate device received 510(k) Clearance under K241853 and since then has been legally marketed in the United States.

2. Do the devices have the same intended use?
Yes, with both devices, users are able to perform brachytherapy cancer treatment where indicated under the direction of clinical professionals. Both devices can be used with HDR brachytherapy.

3. Do the devices have the same technological characteristics?
No, There are differences in the flexibility and configurability that the subject device provides relative to the predicate that addresses varying patient anatomy. However, they are both patient-contacting applicator sets that are intended for use in the same anatomical region. The material composition, general design (Fletcher-Style), and device/environment compatibility is similar between the devices.

4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?
No, these differences do not raise different questions of safety and effectiveness. As demonstrated within this 510(k) submission, these differences raise similar questions relating to usability and performance. These considerations of safety and effectiveness were also applicable to the predicate device, as there are similar configurable elements which can be used to accommodate varying patient anatomy.

5a. Are the methods acceptable?
Yes, these verification and validation methods are similar to those applied to the predicate device and are well established and acceptable for the purpose of evaluation, either through the use of voluntary consensus standards or having been utilized in other 510(k) clearances. Test results demonstrate conformance to applicable requirements specifications and assure hazard safeguards function properly.

5b. Do the data demonstrate substantial equivalence?
Yes, the overall verification and validation testing for the Titanium Flexible Geometry FSD Applicator Set demonstrates that the device requirements and risk control measures perform as intended at a level similar to the predicate.

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 Titanium Flexible Geometry FSD Applicator Set to be as safe and effective as the predicate and therefore substantially equivalent to the predicate device.