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

November 7, 2024

Re: K241853
Trade/Device Name: Titaniuim Fletcher-Style Applicator Set Defined Geometry; Smit Cervical Sleeve
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: June 26, 2024
Received: June 27, 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.

510(k) Number *(if known)*
K241853

Device Name
Titanium Fletcher Style Applicator Set Defined Geometry
Smit Cervical Sleeves

Indications for Use *(Describe)*

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 Smit Cervical Sleeves are indicated for use where any intrauterine tandem is used for 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.

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K241853

Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Titanium Fletcher-Style Applicator Set Defined Geometry

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 Fletcher-Style Applicator Set Defined Geometry,
Smit Cervical Sleeve

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

III. Predicate Device

Titanium Fletcher-Style Applicator Set Defined Geometry (K120731)

Reference Device

INTRACAVITARY BRACHYTHERAPY APPLICATORS SEGMENTED CERVIX APPLICATOR SET (K033371)

IV. Device Description

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 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 Titanium Fletcher-Style Applicator Set Defined Geometry includes patients whose cancer can be treated using HDR or PDR brachytherapy, as determined by the prescribing physician. The Titanium Fletcher-Style Applicator Set Defined Geometry is intended to be used in a healthcare or treatment facility by trained and qualified personnel.

This 510(k) submission is also inclusive of the Smit Cervical Sleeve which is an optional component that may be used with the Titanium Fletcher Style Applicator Set Defined Geometry but is not required to successfully perform the intended use. Please note that some of the documentation that is provided in this submission for the Titanium Fletcher Style Applicator Set Defined Geometry is also inclusive of/applicable to the Smit Cervical Sleeve.

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

- The rigid design allows for a reproducible setup.
- The probes and the central clamping mechanism are made from strong, lightweight titanium which are marked with “Ti” for easy identification.
- 3mm diameter intrauterine tandems allow for easy insertion into the cervical channel helping provide maximum patient comfort.
- Six different intrauterine tandem lengths available allowing for insertion across a range of anatomical sizes (from 3 to 8 cm past the cervical os).
- Integrated cervical stoppers reduce the risk of perforation.
- Channel marking on the intrauterine tandems and colpostat probes for easy identification.
- Flat-edged ovoids to help prevent tissue protrusion between ovoids.
- Four different ovoid sizes to allow for varying anatomy.
- Optional interstitial ovoids allow the additional use of plastic needles for more complex cases.
- Optional needle collectors allow for the fixation of the needles.
- Optional Smit cervical sleeves with markers allow easy multiple fraction application and help provide maximum patient comfort.
- Optional rectal retractor available to help lower rectal doses.
- CT compatible and MR conditional
- HDR and PDR compatible
- Can be manually or machine cleaned, disinfected and is steam sterilizable.
- Can be securely connected to the BRAVOS Afterloader System, GammaMedplus iX and VariSource iX series afterloaders.
- Suitable for patient contact for a period less than 30 days

V. 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 Smit Cervical Sleeves are intended for use when performing HDR or PDR brachytherapy.

VI. 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 Smit Cervical Sleeves are indicated for use where any intrauterine tandem is used for HDR or PDR brachytherapy.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject Device to Predicate Device

FEATURE ANO/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION 5l0(K) ID# K120731 GammaMed Titanium Fletcher-Style Applicator Set GM11006200 GammaMed Titanium Fletcher-style Applicator Set - Defined geometry	NEW/MODIFIED DEVICE NAME GM11006200 Titanium Fletcher- Style Applicator Set - Defined Geometry	COMPARISON
Intended use	The GammaMed Titanium Fletcher-style Applicator Set with defined geometry was developed to treat cancer of the uterus, cervix, endometrium and vagina.	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.	Added paracervix to intended use and clarified product name to Titanium Fletcher-style Applicator Set - Defined Geometry to reflect the broad range of compatible applicator sets as opposed to highlighting only the GammaMed. Although this change adds an additional anatomical site, the manner in which the device is used is consistent with the anatomical area that was originally cleared and does not introduce an additional risk of being used in a generalized treatment application.
Indications for Use	The GammaMed Titanium Fletcher-style Applicator Set with defined geometry was developed for brachytherapy treatment of cancer of the uterus, cervix, endometrium and vagina.	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.	Added paracervix to intended use and clarified product name to Titanium Fletcher-style Applicator Set - Defined Geometry
Labeling	The probes are marked with numbers at the proximal end so that each probe can be individually identified. (Center probe = 1, left probe (patient's left) = 2, right probe (patient's right) = 3)" (PGM11006200_11 EN, dated 2013-07-30)	The probes are marked with numbers at the proximal end so that each probe can be individually identified. (Center probe = 1, right probe (patient's left) = 2, left probe (patient's right) = 3)" (PGM11006200_12 EN, dated 2014-07-09)	Update made for consistency with electronic library
Compatible After loader	GammaMedp/us Series VariSource Series	GammaMedp/us Series VariSource Series BRAVOS Afterloader System	Addition of BRAVOS Afterloader

FEATURE ANO/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION 5I0(K) ID# K120731 GammaMed Titanium Fletcher-Style Applicator Set GM11006200 GammaMed Titanium Fletcher-style Applicator Set - Defined geometry	NEW/MODIFIED DEVICE NAME GM11006200 Titanium Fletcher- Style Applicator Set - Defined Geometry	COMPARISON
Design (Optional Accessories)	Intrauterine Probe with stopper 30°, length: 40mm, 60mm, 80mm (optional 30mm, 50mm, 70mm)	Titanium intrauterine probe with cervical stop 30°, length: 40mm, 60mm, 80mm (optional 30mm, 50mm, 70mm)	Clarified that the material of the intrauterine probe is Titanium
	Mini-colpostat segment, pair Colpostats segment: 20mm, 25mm, 30mm spread	Mini-ovoids, pair Ovoids for 20, 25, 30 mm spread, pair Titanium central clamping mechanism	Re-named the colpostat segment pair to "ovoid" ovoids to harmonize the naming compared to other Varian Applicator sets
	Grub Screw Diameter: 0.25x45◦	Grub Screw Diameter: 0.4x45◦	Diameter change was made to create a better fit between screws
		Central fixation screw for intrauterine probe Fixation screws for colpostat probe	Inclusion of two (2) new optional components that will be available if requested for use with the colpostat probe
Materials	Stainless Steel, PPSU, PEEK, Titanium 3.7025 (Grade 1)	Stainless Steel, PPSU, PEEK, Titanium 3.7035 (Grade 2)	An additional Titanium grade was released to enlarge the delivery availability of the tube for the colpostat and intrauterine probes
Materials	Shallow well of the 4.5mm holder	Shallow well of the 4.5mm holder was removed	The shallow well of the 4.5mm holder was redundant for the three channel applicators; therefore, it was removed.
Materials	Rectal retractor connection rod tube	Rectal retractor connection rod solid material (stainless steel)	Increased improved availability of semi-finished goods

FEATURE ANO/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION 5l0(K) ID# K120731 GammaMed Titanium Fletcher-Style Applicator Set GM11006200 GammaMed Titanium Fletcher-style Applicator Set - Defined geometry	NEW/MODIFIED DEVICE NAME GM11006200 Titanium Fletcher- Style Applicator Set - Defined Geometry	COMPARISON
Packing	Individual	Individual	No change
Sterility	Delivered in non-sterile condition. To be sterilized at customer site. Number of sterilization cycle: 100 & 500 times	Delivered in non-sterile condition. To be sterilized at customer site. Number of sterilization cycle: 250 times & 500 times	Updated number of sterilization cycles to 250 & 500
Sterilization method	Manual and machine cleaning Steam sterilization	Manual and machine cleaning Steam sterilization	No change
Biocompatibility	Fully biocompatible	Fully biocompatible	No change
Anatomical sites	Uterus, cervix, endometrium, and vagina	Uterus, cervix, paracervix, endometrium and vagina	Addition of paracervix anatomical site
Compatibility with the environment and other devices	CT Compatible, MR Conditional	CT Compatible, MR Conditional	No change
Where used	Brachytherapy treatment room	Brachytherapy treatment room	No change

Table 2: Comparison of Subject Device to Reference Device

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION 510(K) ID# K033371 INTRACAVITARY BRACHYTHERAPY APPLICATORS SEGMENTED CERVIX APPLICATOR SET	NEW/ MODIFIED DEVICE NAME APPLICATORS FOR SMIT CERVICAL SLEEVES	Comparison
Intended use	Segmented Cervix Applicator Set is developed to irradiate the cervix, the vagina and the vaginal stump. The applicator set is MR and CT compatible. The cylinder segments can be used with cervical sleeves (Smit), flexible intra-uterine probes or without intra-uterine probes. The segmented construction of the applicator allows an individual adaptation to the patient's anatomy. The maximum implantation time for the Segmented Cervix Applicator is 7 days	The Smit Cervical Sleeves are intended for use when performing HDR or PDR brachy- therapy.	Creation of intended use to be consistent with Titanium Fletcher Style Applicator Set Defined Geometry
Indications for Use	Segmented Cervix Applicator Set is developed to irradiate the cervix, the vagina and the vaginal stump. The applicator set is MR and CT compatible. The cylinder segments can be used with cervical sleeves (Smit), flexible intra-uterine probes or without intra-uterine probes. The segmented construction of the applicator allows an individual adaptation to the patient's anatomy. The maximum implantation time for the Segmented Cervix Applicator is 7 days	The Smit Cervical Sleeves are indicated for use where any intrauterine tandem is used for HDR or PDR brachytherapy.	Creation of intended use to be consistent with Titanium Fletcher Style Applicator Set Defined Geometry
Compatible After- loader	GammaMedplus Series VariSource Series	GammaMedplus Series VariSource Series BRAVOS Afterloader System	Addition of BRAVOS afterloader system
Design	Cervical Sleeves Smit cervical sleeve diameter 6 mm, lengths 30, 40, 50, 60, 70, 80 mm	Smit cervical sleeves: Diameter 6 mm, lengths 30, 40, 50, 60, 70, 80 mm	No change
Materials	Cervical Sleeves PPSU, Titanium (marking screw)	PPSU, Titanium	No change
Packing	Individual	Individual	No change
Sterility	Delivered in non-sterile condition. To be sterilized at customer site.	Delivered in non-sterile condition. To be sterilized at customer site.	No change
Sterilization method	Steam sterilization	Steam sterilization	No change
Biocompatibility	Fully biocompatible	Fully biocompatible	No change
Anatomical sites	Cervix, Vagina, and Vaginal Stump	Uterus, cervix, paracervix, endometrium, and vagina	Addition of uterus, paracervix, and endometrium
Compatibility with the environment and other devices	CT Compatible, MR Conditional	CT Compatible, MR Conditional	No change
Where used	Brachytherapy treatment room	Brachytherapy treatment room	No change

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".

Magnetic Resonance Testing (MR):
MR Compatibility testing was completed, and documentation was provided to FDA in support of the substantial equivalence determination. The Titanium Fletcher-Style Applicator Set Defined Geometry 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

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 Titanium Fletcher-Style Applicator Set Defined Geometry 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

Standard/ CS	Standard/ CS Title
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN 62366-1:2015+Al: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

Standard/ CS	Standard/ CS Title
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/Al: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

Major Changes included:

- Changes to Intended Use and Indications for Use Statements
  - Addition of wording "HDR and PDR brachytherapy"
  - In comparison to the previous 510(k) submission there is an expansion of the indications for use to include a new anatomical site "paracervix".

    It is important to note that although this change adds an additional anatomical site, the manner in which the device is used is consistent with the anatomical area that was originally cleared and does not introduce an additional risk of being used in a generalized treatment application. The overall intended use to treat cancer with brachytherapy is unchanged. While there are changes to the wording of the statements, overall intended use is not changed.

  - Clarified product name to: The Titanium Fletcher-style Applicator Set – Defined Geometry
- Number of sterilization cycle changed from 100 & 500 times to 250 times & 500 times.
- Deletion of warning regarding the use of plastic needles. Due to implementation of new plastic needles that are MR Safe (ISD 14) are tested for 25 reuses as opposed to single use.
- Added compatibility to the BRAVOS Afterloader System
- Added optional accessories to complete the list

Cumulative changes since the most recent 510(k) filing in 2012 are also included and detailed within the submission.

In addition, we are requesting clearance for the cervical sleeves. The cervical sleeves were previously cleared for use in K033371. The device itself is unchanged however we are adding a separate indication for use statement for the Cervical sleeves with this submission.

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 Titanium Fletcher-Style Applicator Set Defined Geometry to be as safe and effective as the predicate and therefore substantially equivalent to the predicate device.