May 20, 2026

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

Re: K252717
Trade/Device Name: MAASTRO Rectal Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: August 27, 2025
Received: August 28, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JULIE SULLIVAN -S

Julie Sullivan, Ph.D.
Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252717

Device Name
MAASTRO Rectal Applicator Set

Indications for Use *(Describe)*
The MAASTRO Rectal Applicator Set is intended for use for cancer treatment of the rectum 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.

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

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Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for MAASTRO Rectal 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: May 19th, 2026

II. Device Information

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

III. Predicate Device

Universal Cylinder Applicator Family (K193240)

IV. Device Description

The MAASTRO Rectal Applicator Set enables HDR treatment of rectal cancer. This involves inserting a proctoscope and applicator through the anus and placing it in close contact with the tumor. The dilator enables smooth insertion. The Illumination Adapter serves as interface to an external illumination device.
The Targeting Window Applicator allows positioning control and adjustment of the treatment position. All this can be fixed to the proctoscope using the fixation screw. The Applicator for Proctoscope and Dilator for Proctoscope components are designed for single use.

Key performance characteristics are as follows:

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

- Not CT Compatible
- MR Compatibility: Unsafe
- The Proctoscope is placed eye-guided allowing placement close to the tumor
- The cylindrical Applicator containing channels is inserted into proctoscope up to the tumor
- The channels within the Applicator are aligned to allow uniform high dose delivery to the tumor
- Healthy tissue is spared from radiation by shielding

V. Intended Use

The MAASTRO Rectal Applicator Set is intended for use for cancer treatment of the rectum 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: Universal Cylinder Applicator Family (K193240)** ***specifically, the universal multi-channel cylinder set***	**Subject Device: MAASTRO Rectal Applicator Set**	**Comparison**
Intended use	The Universal Multi-Channel Cylinder Set is intended for use when performing HDR or PDR brachytherapy within a CT or MRI environment.	The MAASTRO Rectal Applicator Set is intended for use for cancer treatment of the rectum using HDR brachytherapy.	Use only in the rectum for cancer treatment by means of HDR brachytherapy Please note, the subject device is being compared specifically to the multi-channel cylinder set from the predicate device.
Indications for Use	The Universal Multi-Channel Cylinder Set are indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium, and rectum using HDR or PDR brachytherapy.	The MAASTRO Rectal Applicator Set is indicated for use for cancer treatment of the rectum using HDR brachytherapy	Use only in the rectum for cancer treatment by means of HDR brachytherapy

Feature and/or Specification of new/modified device	Predicate Device: Universal Cylinder Applicator Family (K193240) **specifically, the universal multi-channel cylinder set*	Subject Device: MAASTRO Rectal Applicator Set	Comparison
Patient Target Group	N/A	The patient target group includes adult patients of 18 years and above whose cancer can be treated using HDR brachytherapy, as determined by the prescribing physician.	Clarification that the intended patient population is limited to adults only.
Compatible Afterloader	GammaMedplus Afterloader Series VariSource 200 and iX Afterloader BRAVOS Afterloader System	GammaMedplus Afterloader Series BRAVOS Afterloader System	The subject device is not compatible with the VariSource 200 and iX Afterloader due to product being end of service at the end of 2025.
Design	**Components:** * Please note, the subject device is being compared specifically to the multi-channel cylinder set from the predicate device.	**Components:**	

Feature and/or Specification of new/modified device	Predicate Device: Universal Cylinder Applicator Family (K193240) **specifically, the universal multi-channel cylinder set*	Subject Device: MAASTRO Rectal Applicator Set	Comparison
	Universal Multi-channel Cylinder Set: Diameters 25, 30, 35, 40 mm Rigid Guide Tube 250 mm length Clamping segment	MAASTRO rectal cylindrical applicator: diameters 20 and 24 mm Proctoscope: diameters 26 and 30 mm (requesting clearance with this submission) Dilator: diameters 20 and 24 mm Illumination adapters: for proctoscope diameter 26 mm, and proctoscope diameter 30 mm Targeting Window applicator for proctoscope diameter 26 mm and proctoscope diameter 30 mm. Fixation Screw	The MAASTRO Rectal Applicator Set is a new device that is indicated specifically for treatment of cancer in the rectum. The differences in dimension of the cylindrical applicator of the MAASTRO Rectal Applicator Set are due to the treatment design for the rectum. The proctoscope is specifically needed to access to the rectum, but functions as a 'guide' to the treatment area in conjunction with the dilator, illumination adapters, and targeting window applicator similar to the rigid guide tube and clamping segment. Similar to the Multi-Channel Cylinder Set, the rectal cylindrical applicator includes multiple channels which are inserted into a proctoscope through the anus and placing it in close contact with the tumor.
Materials	PPSU (Polyphenylsulfone) PEEK (Polyether ether ketone) Titanium	Polyamide (PA) 2200 Stainless Steel PEEK (Polyether ether ketone)	While the MAASTRO Rectal Applicator Set is a new device and is comprised of different biocompatible material-, the materials used in the subject device have been tested to and comply with the same biological standards as the predicate device. Furthermore, the materials of the subject device are from common polymers and metals with well-established biocompatibility profiles.

Feature and/or Specification of new/modified device	Predicate Device: Universal Cylinder Applicator Family (K193240) **specifically, the universal multi-channel cylinder set*	Subject Device: MAASTRO Rectal Applicator Set	Comparison
Packing	Individual	Individual	Similar
Sterility	Provided non-sterile	Provided non-sterile	Similar
Sterilization method (Bronchial catheter and Monofil)	Steam Sterilization 132°C for 4 min 134°C for 3 min 134°C for 5 min	Steam Sterilization 132°C for 4 min 134°C for 3 min 134°C for 5 min Or High-Level Disinfection	Added high level disinfection for consistency with other, Varian applicator sets
Reprocessing	Universal Multi-Channel Cylinder: 100 cycles Rigid Guide Tube, 250 mm length: 500 cycles Clamping segment: 500 cycles	Applicator: Single Use Proctoscope: 200 cycles Dilator: Single Use Illumination adapters: 200 cycles Targeting Window applicator: 200 cycles	Based on materials and testing, the MAASTRO Rectal Applicator Set is comprised of single use and reusable components.
Biocompatibility	Fully biocompatible	Fully biocompatible	Similar
Anatomical sites	Vagina, vaginal stump, cervix, endometrium, uterus, and rectum	Rectum	The subject device is indicated for use only in the rectum

Feature and/or Specification of new/modified device	Predicate Device: Universal Cylinder Applicator Family (K193240) **specifically, the universal multi-channel cylinder set*	Subject Device: MAASTRO Rectal Applicator Set	Comparison
Compatibility with the environment and other devices	CT compatible MR Conditional	Not CT compatible MR Unsafe	The MAASTRO Rectal Applicator Set is partially made of metallic and conductive materials and is, therefore, unsafe in a magnetic environment
Where used	Brachytherapy treatment room	Brachytherapy treatment room	Similar

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

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

Dose Distribution:

The following literature provides guidance on dose prescription and fractionation:

- Jean-Pierre Gerard et al, paper, Targeted Radiotherapy Using Contact X-ray Brachytherapy 50 kV: This paper provides guidance on appropriate tumor staging for contact brachytherapy.
- Murillo Bellezzo et al, paper, Advanced design, simulation, and dosimetry of a novel rectal applicator for contact brachytherapy with a conventional HDR 192Ir source: This paper explains how the MAASTRO applicator design uses HDR 192Ir sources to deliver a dose distribution similar to those of contact X-ray brachytherapy devices. The paper also discusses the depth dose curves that this device can achieve.

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, and Sensitization.

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:
MAASTRO Rectal 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.

- Mechanical Stability Testing: The applicator was tested to withstand mechanical loads which occur during normal application without functional damage. The device maintained structural integrity and functional performance following repeated use and reprocessing cycles and application of 20N pull force.

- Dose Profile: Testing demonstrated that the applicator provides a suitable dose distribution within the target region, including acceptable range of surface dose and dose fall-off. Evaluation of dose distribution confirmed that shielding features and applicator design effectively limit radiation exposure to surrounding tissue, consistent with design requirements.

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 MAASTRO Rectal Applicator Set is MR Unsafe. This testing was conducted in accordance with ASTM F2503 –23 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 MAASTRO Rectal 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.

Standard Number	Standard Title
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

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