May 9, 2025

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

Re: K250299
Trade/Device Name: CT/ MR Tandem and Ovoid Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: April 14, 2025
Received: April 14, 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 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)*

K250299

Device Name

CT/ MR Tandem and Ovoid Set

Indications for Use *(Describe)*

The CT/MR Tandem and Ovoid Set is indicated for use for cancer treatment of the uterus, cervix, paracervix, endometrium, and vagina 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 CT/MR Tandem and Ovoid 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: CT/MR Tandem and Ovoid 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 CT/MR Tandem and Ovoid Set is a gynecological brachytherapy applicator intended for use for cancer treatment of the uterus, cervix, paracervix, endometrium, and vagina using HDR brachytherapy.

The CT/MR Tandem and Ovoid Set is an applicator for intracavitary and interstitial 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 radioactive source is provided by an afterloader.

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 applicator is inserted into the patient and connected to an afterloader. This combination places the remote-controlled radioisotope treatment source nearby the target tissue. The applicator guides the radioactive source to the correct location or locations for treatment. The CT/MR Tandem and Ovoid Set is MR safe and CT compatible.

The CT/MR Tandem and Ovoid Set includes patients whose cancer can be treated using HDR brachytherapy, as determined by the prescribing physician. The CT/MR Tandem and Ovoid Set is intended to be used in a radiation therapy or radiation oncology department in a hospital environment by trained and qualified personnel.

This applicator set includes several parts, such as intrauterine tandems, interstitial ovoids, guide tubes, and optional rectal retractors. It is designed to be used with MR and CT imaging, and the components come in different sizes and angles to suit different patient anatomies. It also includes a needle tandem for specific situations and can be used for up to 30 days in some cases.

V. Intended Use

The CT/MR Tandem and Ovoid Set is a gynecological brachytherapy applicator intended for use for cancer treatment of the uterus, cervix, paracervix, endometrium, and vagina using HDR brachytherapy.

VI. Indications for Use

The CT/MR Tandem and Ovoid Set is indicated for use for cancer treatment of the uterus, cervix, paracervix, endometrium, and vagina using HDR brachytherapy

VII. Comparison of Technological Characteristics with the Predicate Device

The following comparison table below demonstrates the substantial equivalence of the subject CT/MR Tandem and Ovoid Set to the predicate device Titanium Fletcher-Style Applicator Set Defined Geometry [K241853].

The differences between the subject and predicate are indicated in blue fill. Please refer to the Substantial Equivalence Discussion attached with this submission for a more in depth comparison between the devices.

FEATURE AND/OR SPECIFICATION OF NEW/ MODIFIED DEVICE	**CLEARED DEVICE FEATURE/SPECIFICATION** **Titanium Fletcher-Style Applicator Set Defined Geometry [510(k) ID# K241853]** **Titanium Fletcher-style Applicator Set - Defined geometry**	**SUBJECT DEVICE** **CT/MR Tandem and Ovoid 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 CT/MR Tandem and Ovoid Set is intended for use for cancer treatment of the uterus, cervix, paracervix, endometrium, and vagina using HDR brachytherapy.	**Substantially Equivalent** PDR not supported for new applicators

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 CT/MR Tandem and Ovoid Set is indicated for use for cancer treatment of the uterus, cervix, paracervix, endometrium, and vagina using HDR brachytherapy	**Substantially Equivalent** PDR not supported for new applicators
Labeling	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)	The probes are marked with numbers at the proximal end so that each probe can be individually identified Center tandem (one marking) = Channel 1 Left colpostat/patient's left (two markings) = Channel 2 Right colpostat/patient's right (three markings) = Channel 3 (P1057168-003-C, OCTOBER 2024)	**Substantially Equivalent** PDR not supported for new applicators
Compatible After loader	GammaMedplus Series VariSource Series BRAVOS Afterloader System	GammaMedplus Afterloader series BRAVOS Afterloader System	**Substantially Equivalent** The VariSource Afterloader series was obsolete on Dec 25, 2024, and will not be supported anymore.
Design (Optional Accessories)	Titanium intrauterine probe with cervical stop 30°, length: 40mm, 60mm, 80mm (optional: 30mm, 50mm, 70mm) Mini-ovoids (colpostat), pair Ovoids for 20, 25, 30 mm spread, pair Titanium central clamping mechanism Grub Screw: 0,4x45° Diameter Colpost probe and fastening screw made of Stainless Steel Central fixation screw for intrauterine probe Fixation screws for colpostat probe	Colpostat probes: left and right Intrauterine tandem dimension: 15°, 30° and 45°, each with 2, 4, 6 cm Intrauterine needle tandem 30° Ovoid pairs for 13, 20, 25, 30 and 40 mm spread Interstitial ovoids pairs for 14.5, 20, 25, 30 and 40 mm Assembly Module CT/MR Guide tube Collector CT/MR Clamping Unit CT/MR Retraction Nut CT/MR Disassembly Pin CT/MR Leak Stop Channel markers Cleaning caps	**Different** The new device has several new and redesigned sub-items

Materials	Stainless Steel, PPSU, PEEK, Titanium 3.7035 (Grade 2)	PEEK, PAEK	**Different** Subject device is comprised of different materials (PEEK and PAEK)
Packing	Individual	Individual	Equivalent
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 cycle: 100 times	**Different** Number of sterilization cycles limited by material characteristics
Sterilization method	Manual and machine cleaning Steam sterilization	Manual and machine cleaning Steam sterilization	Equivalent
Biocompatibility	Fully biocompatible	Fully biocompatible	Equivalent
Anatomical sites	Uterus, cervix, paracervix, endometrium and vagina	Uterus, cervix, paracervix, endometrium and vagina	Equivalent
Compatibility with the environment and other devices	CT compatible MR conditional	CT compatible MR safe	**Different** Subject device is MR safe
Where used	Brachytherapy treatment room	Radiation therapy or radiation oncology department	Equivalent Brachytherapy can only be used in a dedicated environment for radiation therapy.

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 CT/MR Tandem Ovoid Set is MR Safe and complies with the following MR standard:

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

Since CT/MR Tandem and Ovoid Set is made from non-metallic, non-magnetic material, no testing is performed according to the following standards.

- 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 F2182-19: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

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 CT/MR Tandem Ovoid 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'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+Al:2020	Application of Usability Engineering to Medical Devices
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 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/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

IX. Determination of Substantial Equivalence to the Predicate

The intended use and indications for use for the subject are substantially equivalent to the predicate device. The subject device does not cover PDR Brachytherapy, whereas the predicate is intended for use in both HDR and PDR brachytherapy. The subject device has several new components as a part of its design, which were also added to the labeling for completeness.

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. While the predicate device is MR compatible due to its carefully designed metallic components, the subject device is deemed MR safe as it is fully non-metallic and non-conductive.

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 CT/MR Tandem and Ovoid Set to be as safe and effective as the predicate and to perform at least as well as the predicate device (K241853)