



November 19, 2025

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

Re: K252884

Trade/Device Name: Guided Aarhus Applicator Set  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote Controlled Radionuclide Applicator System  
Regulatory Class: Class II  
Product Code: JAQ  
Dated: September 9, 2025  
Received: September 10, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lora Weidner". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

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

## Indications for Use

510(k) Number (if known)  
K252884

Device Name  
Guided Aarhus Applicator Set

### Indications for Use (Describe)

The Guided Aarhus Applicator Set is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, and endometrium 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## Premarket Notification - 510(k) Summary

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Traditional 510(k) Submission for Guided Aarhus 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](mailto:submissions.support@varian.com)

Date Prepared: November 7, 2025

### II. Device Information

Proprietary Name: Guided Aarhus Applicator Set

Classification Name: Remote controlled radionuclide applicator system

Regulation Number: §892.5700

Product Code: JAQ

### III. Predicate Device

Aarhus Applicator Set (K222775)

The Aarhus Applicator Set is intended for use when performing HDR or PDR brachytherapy within a CT or MRI environment.

The Aarhus Applicator Set is indicated for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy within a hospital CT or MRI environment.

### IV. Device Description

The Guided Aarhus Applicator Set is an applicator for intracavitary/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.

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.

### V. Intended Use and Indications for Use

Intended Use

The Guided Aarhus Applicator Set is intended for use when performing HDR brachytherapy within a CT or MRI environment.

**Indications for Use**

The Guided Aarhus Applicator Set is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, and endometrium using HDR brachytherapy.

The indications have been expanded to be more specific. The endometrium is part of the uterus but specifically the inner lining. The Vagina and the vaginal stump are related but the stump is the tissue remaining after a hysterectomy – this can be treated when the Guided Aarhus template is used in conjunction with the Guiding tube 60° ring for central needle (GM11013960). This change to the indication does not affect the safety or effectiveness of the device as the use of the template does not change based on this indication change.

The intended use has been updated to remove Pulse Dose Rate (PDR) as we are no longer expanding our applicator range for PDR use as we are removing support for this machine in the future.

There are minor changes made to the intended use and indications for use that do not affect the safety and effectiveness of the device when used as labelled. The core clinical application, target patient population, and intended user remain consistent with the predicate.

**VI. Comparison of Technological Characteristics with the Predicate Device**

The modifications include:

- Modification to the intended and indications for use
- Removed material UHU-plus endfest 300
- Removal of VariSource as compatible afterloader
- Additional ring diameter of 28mm
- Addition of guide tube collectors
- Steam sterilization is available for 18 min at 134C
- Anatomical sites now additionally include the vaginal stump and endometrium

<b>Feature and/or Specification</b>	<b>Predicate Device: Aarhus Applicator Set (K222775)</b>	<b>Subject Device: Guided Aarhus Applicator Set (K252884)</b>
Intended Use	The Aarhus Applicator Set is intended for use when performing HDR or PDR brachytherapy within a CT or MRI environment.	The Guided Aarhus Applicator Set is intended for use when performing HDR brachytherapy within a CT or MRI environment.
Indications for Use	The Aarhus Applicator Set is indicated for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy within a hospital CT or MRI environment.	The Guided Aarhus Applicator Set is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, and endometrium using HDR brachytherapy.
Design	<p><b>Aarhus Applicator Set</b></p> <p>Aarhus Vaginal Template:</p> <ul style="list-style-type: none"> <li>• Ring-shape template in 60°.</li> <li>• Ring diameter 32 mm and 36 mm.</li> <li>• Straight and oblique needle-guiding holes.</li> </ul>	<p><b>Guided Aarhus Applicator Set</b></p> <p>Guided Aarhus vaginal template:</p> <ul style="list-style-type: none"> <li>• Ring-shape template in 60°.</li> <li>• Ring diameter 28 mm, 32 mm, 36 mm.</li> <li>• Straight and oblique needle-guiding holes.</li> </ul>

**510(k) Summary - K252884**

Traditional 510(k) Application  
Guided Aarhus Applicator Set

	Needle Collector	Guide Tube Collectors for up to 7 and 11 needles. Guiding tube 60° for a central needle.
Compatible Afterloader	GammaMedplus Afterloader Series VariSource Afterloader Series BRAVOS Afterloader System	GammaMedplus Afterloader Series BRAVOS Afterloader System
Materials	Vaginal Template: <ul style="list-style-type: none"> <li>• Victrex PEEK 450 G and PEEK 381 G</li> <li>• EPO-TEK OD2002 (Epoxy)</li> <li>• UHU-plus endfest 300</li> </ul> Needle Collector: <ul style="list-style-type: none"> <li>• Victrex PEEK 450 G</li> </ul>	Vaginal Template and Guiding Tube: <ul style="list-style-type: none"> <li>• Victrex PEEK 450 G and PEEK 381 G</li> <li>• EPO-TEK OD2002 (Epoxy)</li> </ul> Guide Tube Collector: <ul style="list-style-type: none"> <li>• Victrex PEEK 450 G</li> </ul>
Packing	Individual	Individual
Sterility	Provided non-sterile	Provided non-sterile
Sterilization Method	Steam sterilization <ul style="list-style-type: none"> <li>• 4 minutes at 132°C</li> <li>• 3 minutes at 134°C</li> <li>• 5 minutes at 134°C</li> </ul>	Steam sterilization <ul style="list-style-type: none"> <li>• 4 minutes at 132°C</li> <li>• 3 minutes at 134°C</li> <li>• 5 minutes at 134°C</li> <li>• 18 minutes at 134°C</li> </ul>
Biocompatibility	Full biocompatibility	Full biocompatibility
The Anatomical Sites	Vagina, cervix and uterus	Vagina, vaginal stump, cervix, uterus and endometrium
Environment	CT compatible MR-Safe for components of the Aarhus Applicator Set.  MR-Conditional for the Aarhus Applicator Set in combination with plastic interstitial needles and intrauterine tandems.	CT compatible MR-Safe for components of the Guided Aarhus Applicator Set.  MR-Conditional for the Guided Aarhus Applicator Set in combination with intrauterine tandems.
Where Used	Brachytherapy treatment room	Brachytherapy treatment room

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

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

### Biocompatibility Testing:

The biocompatibility evaluation for the subject device was conducted according to ISO 10993-1 ‘Biological Evaluation of a Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process.’ This includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogenicity
- Acute Systemic Toxicity

### 510(k) Summary - K252884

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Guided Aarhus Applicator Set

- Subacute Toxicity
- Implantation
- Chemical Characterization
- Toxicological Risk Assessment

The reports for the previous submission Aarhus Applicator Set K222775 is used to leverage the subject device Guided Aarhus Applicator Set. Please see the attachment Biological Evaluation for more information.

**Sterilization Testing:**

Sterilization testing for the subject device was conducted to assess the effectiveness of the provided cleaning, disinfection, and sterilization procedures for the device. Furthermore, the components of the subject set were subjected to sterilization cycles up to the stated use life and evaluated for performance and any damage that might affect the safety or effectiveness.

**Electrical Safety and Electromagnetic Compatibility (EMC):**

This item is not applicable to the subject device. No electrical safety and electromagnetic compatibility tests have been included in this submission in support of the substantial equivalence determination.

**Magnetic Resonance (MR):**

MR compatibility rationale was included as a summary. The vaginal templates, guiding tube, and guide tube collector are made from non-metallic, non-magnetic material, that are non-conducting. Therefore, no magnetically induced displacement force, magnetically induced torque, or radiofrequency induced heating may occur. No tests according to the standard ASTM F2052-21, ASTM F2213-17, or ASTM F2182-19 are required.

**Software Verification and Validation Testing:**

This item is not applicable to the subject device. The devices do not contain or consist of software/firmware. No software verification and validation testing have been included in this submission in support of the substantial equivalence determination.

**Mechanical Testing:**

Guided Aarhus Applicator Set has undergone formal design verification and design validation testing. The applicator was tested to withstand a minimum of 30N push and pull forces applied to templates shaft in axial direction while the ring is fixed and 30N between assembled template and tandem while template is fixed. Applicator and components were also tested to withstand the drop test as defined in IEC 60601-1 (drop of applicator in different orientations from a height of 1 m onto Hardwood Board). Both tests passed successfully. Design verification and design validation testing demonstrate that the subject device performs as intended. No acoustic testing was performed

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.

**Human Factors:**

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. Participants performed two tasks using the Guided Aarhus Applicator Set as they would in their clinic. The collected

Usability Key Performance Indicators (KPIs) show that the evaluation has passed as no (safety) use errors were observed, and participants completed all tasks within the required (safe) time.

**Use of Consensus Standards:**

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the device’s substantial equivalency to the predicate:

ANSI/AAMI/ISO 14971:2019	Medical devices - Applications of risk management to medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62366- 1:2015+A1:2020	Application of Usability Engineering to Medical Devices
AAMI TIR12:2020	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
ANSI/AAMI ST98:2022	Cleaning Validation of health care products –cleaning process for medical devices
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
ANSI/AAMI/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 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
ISO/TS 17665-2:2009	Sterilization of health care products –Moist heat –Part 2: Guidance on the application of ISO 17665-1
ASTM D4332-22	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D4169:2009	Standard Practice for Performance Testing of Shipping Containers and Systems
ANSI/AAMI/ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
ANSI/AAMI/ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
ANSI/AAMI/ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ANSI/AAMI/ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-12:2021	Biological evaluation of medical devices –Part 12: Sample preparation and reference materials

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ANSI/AAMI/ISO 10993-17:2002	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
ANSI/AAMI/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
IEC 60601-1:2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-17:2013	Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment
ASTM F2503-23	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 11138-7:2019	Sterilization of health care products – Biological indicators – Part 7: Guidance for the selection, use and interpretation of results
ASTM F3293-18	Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Devices
ASTM F3208-20	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Devices

**VIII. Determination of Substantial Equivalence to the Predicate**

There are no changes in the design or principle of operation of the devices. Varian believes the major technological characteristics are substantially equivalent to the predicate device.

The indications have been expanded to be more specific to include the endometrium, vagina, and vaginal stump. This change to the indication does not affect the safety or effectiveness of the device as the use of the template does not change based on this indication change. The intended use has been updated to remove Pulse Dose Rate (PDR) as we are removing support for this machine in the future.

The results of verification and validation as well as conformance to relevant safety standards demonstrate that the device meets the safety and performance criteria. Conclusions drawn from performance tests demonstrate substantial equivalence (SE). Varian considers Guided Aarhus Applicator Set to be substantially equivalent to the predicate device (K222775).