Varian Medical Systems, Inc
% Dr. Lynn Allman
Sr. Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO, CA 94304

May 9, 2024

Re: K240495
Trade/Device Name: Flexible Fixation Device for Gynecological Applicators
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: February 20, 2024
Received: February 20, 2024

Dear Dr. 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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240495

Device Name
Flexible Fixation Device for Gynecological Applicators

Indications for Use *(Describe)*
The Flexible Fixation Device for gynecological applicators is intended for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium or rectum using 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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Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Flexible Fixation Device for Gynecological Applicators

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: April 23, 2024

II. Device Information

Proprietary Name: The Flexible Fixation Device for Gynecological Applicators
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Shielded Applicator Set, Cervical Stop (K151657)

IV. Device Description

The Flexible Fixation Device for Gynecological Applicators is an accessory used to hold an applicator in place, to prevent movement of the applicator during the imaging (standard radiograph, CT and/or MR technique) and treatment process for HDR and PDR brachytherapy.

The key performance characteristics of the device are as follows:

- Fixation rings for cylinders of various diameters (20 mm - 40 mm); and fixation straps (500 mm/150 mm, 1050 mm /350 mm, 1700 mm/500 mm)
- CT compatible
- MR safe
- Fixation rings are sterilizable and released for 250 reuses
- Fixation plate rings are sterilizable and released for 50 reuses
- The fixation straps are qualified for 50 textile laundering cycles
- Suitable for patient contact—on intact skin—for a period of less than 30 day

Fixation straps are fixed in slots of the fixation plate and around the waist of the patient. The fixation ring is attached onto an applicator which then is inserted into the patient. The flexible fixation plate is attached over the applicator and clamped in the collar of the fixation ring. The applicator is connected to an afterloader. This combination places the remote-controlled radioisotope treatment source (brachytherapy source) nearby the target tissue. The applicator guides the radioactive source to the correct location or locations for treatment.

The fixation rings for cylinders of ø 20, 23-, 26-, 30-, 35-, and 40-mm diameter, in combination with the flexible fixation plate, provide a mount for the respective cylinder applicator. The flexible fixation plate for gynecological applicators has a smaller and a larger teardrop-shaped holes for the different fixation rings. It also provides several slots for the fixation straps. The fixation straps of different lengths (500 mm/150 mm, 1050 mm/350 mm, 1070 mm/500 mm) can be fixed at the fixation plate through the slots of the plate using hook-and-loop fasteners. Multiple straps in suitable lengths can be combined and fixated around the patient's waist and if necessary, additionally around the shoulders.

V. Intended Use

The Flexible Fixation Device for gynecological applicators is intended for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium or rectum using HDR or PDR Brachytherapy.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject Device to Predicate Device

Feature and/or Specification	Predicate Device: Shielded Applicator Set, Cervical Stop K151657 (GM11001960 Flexible Fixation device for Gynecological Applicators is listed as an optional accessory of the Shielded Applicator Set)	Subject Device: Flexible Fixation Device for Gynecological Applicators	Comparison
Intended Use	The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy.	The Flexible Fixation Device for gynecological applicators is intended for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium or rectum using HDR or PDR Brachytherapy.	A separate intended use statement is now defined for the Flexible Fixation Device for Gynecological Applicators.
Indications for Use	The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy. The Flexible Fixation Device is a clinical use accessory for the fixation of gynecological applicators.	The Flexible Fixation Device for gynecological applicators is indicated for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium or rectum using HDR or PDR Brachytherapy.	A separate intended use statement is now defined for the Flexible Fixation Device for Gynecological Applicators.
Compatible Afterloader	VariSource iX™ VariSource 200™ GammaMedplus iX™ GammaMedplus 3/24 iX™ BRAVOS Afterloader System	VariSource iX™ VariSource 200™ GammaMedplus iX™ GammaMedplus 3/24 iX™ BRAVOS Afterloader System	No Change

Compatible Applicators	Shielded Applicator Set Stump Applicator Set with CT Cylinders Vaginal Applicator Set with CT Cylinders Segmented Cylinder Applicator Set Cervix Applicator Set Segmented Cervix Applicator Set Applicators used with the Optional Component: Ring Applicator Set 45° Ring Applicator Set 60° Ring Applicator Set 90°	Shielded Applicator Set Universal Stump Applicator Set Universal Segmented Cylinder Applicator Set Universal Multi-channel Cylinder Set Universal Interstitial Cylinder Set Applicators used with the Optional Components: Ring Applicator Set 45° Ring Applicator Set 60° Ring Applicator Set 90° **3D Interstitial Ring Applicator Set 60° (without needle use)** **3D Interstitial Ring Applicator Set 90° (without needle use)**	The cylinder applicators have been updated to the new Universal family. The same range of diameters is covered with the addition of some 40 mm diameter cylinders. The Interstitial ring applicators have been added. Without needle use they are equivalent to the ring sets.
Optional Components	Clamping screw of the fixation ring Bracket for ring applicator for flexible fixation GYN	Clamping screw of the fixation ring Bracket for ring applicator for flexible fixation GYN	No Change
Design	Cylinder: - Ø 20, 23, 26, 30, 35mm - length 140mm Applicator probe: - Ø 3.0mm, straight - length 320mm Tungsten Alloy Shielding: - 90°, 180° - Length 122.5mm Marking Screw (shielded) - 0°, 90°, 2 x 90°, 180°, 270° Clamping Nut for marking screw Clamping screw for probe, 3 mm Plexiglass Filler Piece, 90° Blue Cleaning **Fixation Ring for Cylinder:** **Ø 20, 23, 26, 30, 35, 40 mm** **Flexible Fixation Plate for gynecological applicators** **Fixation strap:** **- 500mm/150mm** **- 1050mm/350mm** **- 1700mm/500mm**	Fixation Ring for Cylinder: Ø 20, 23, 26, 30, 35, 40 mm Flexible Fixation Plate for gynecological applicators Fixation strap: - 500mm/150mm - 1050mm/350mm - 1700mm/500mm	No Change
Materials	The Shielded Applicator Set - Shielding - Tungsten Alloy	- Fixation ring for cylinder – PPSU	Change in material of the

	- Marking Screw, Clamping nut/Screw and applicator probe – Stainless Steel - Cylinder – PMMA - Cleaning cap – Silicone **The Flexible Fixation Device** **- Fixation ring for cylinder – PPSU** **- Flexible fixation plate – PVC** **- Fixation strap – Cotton/PA**	- Flexible fixation plate – **Silicone** - Fixation strap – Cotton/PA	flexible fixation plate from PVC to silicone.
Environment	The Shielded Applicator Set is a clinical use accessory for the fixation of gynecological applicators. CT image compatible and MR-Safe.	The Flexible Fixation Device is a clinical use accessory for the fixation of gynecological applicators. CT image compatible and MR-Safe.	No Change

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

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

Biocompatibility Testing:
The compatibility of the skin-contact component material in the finished product meets the biocompatibility requirements. The Biological Evaluation Tests are in compliance with the standards of ISO 10993-1 and its applicable parts, "Biological Evaluation of Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process".

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:
The Flexible Fixation Device for Gynecological Applicators 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.

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 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices –Part 2: Non-critical medical devices
EN ISO 11138-1:2017	Sterilization of health care products –Biological indicators – Part 1: General requirements
EN ISO 11138-3:2017	Sterilization of health care products –Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
EN ISO 11138-7:2019	Sterilization of health care products –Biological indicators – Part 7: Guidance for the selection, use and interpretation of results
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices –Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11737-1:2018+A1:2021	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2019	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
ISTA 3A (2018)	General Simulation Performance Tests for packaged-products weighing 150 lb. (70 kg) or less (standard, small, flat or elongated)
EN ISO 10993-1:2018	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
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 10993-12:2021	Biological evaluation of medical devices –Part 12: Sample preparation and reference materials
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

VIII. Determination of Substantial Equivalence to the Predicate

The Flexible Fixation Device for Gynecological Applicators was previously sold as an optional accessory for the Shielded Applicator set in K151657. 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 Flexible Fixation Device for Gynecological Applicators to be as safe and effective as the predicate and therefore substantially equivalent to the predicate device.