Varian Medical Systems Inc.
℅ Lynn Allman
Director Regulatory Affairs
3100 Hansen Way
M/s E-110
PALO ALTO, CA 94304

April 9, 2024

Re: K232623
Trade/Device Name: Universal Endometrial Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ
Dated: March 7, 2024
Received: March 11, 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.

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)*
K232623

Device Name
Universal Endometrial Applicator Set

Indications for Use *(Describe)*
The Universal Endometrial Applicator Set is indicated for use for treating cancer of the vagina, cervix, endometrium and uterus 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.

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

The following information is provided according to 21 CFR 807.92.

Submitter:	Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304	Contact Name: Lynn Allman E-mail: submissions.support@varian.com Date: March 2024

Trade/ Proprietary Names:	**Universal Endometrial Applicator Set**	
	Common/Usual Name: **Afterloader System** Source Guide Tubes, Brachytherapy Accessory **Classification Name**: Remote controlled radionuclide applicator system, 21 CFR §892.5700 **Product Code:** JAQ	**Predicate Device:** VariSource Endometrial Applicator for VariSource HDR Afterloader (K980576)
Device Description:	The **Universal Endometrial Applicator Set** (GM11009840) consists of key device components and accessories made of titanium tandems and PEEK vaginal cylinder to allow for adaptation to individual anatomical situations for intracavitary brachytherapy. The Applicator is inserted into the patient and connected to an afterloader. The applicator acts to guide the radioactive source from the afterloader to the correct location or locations for treatment. This combination places the remote-controlled radioisotope treatment source (brachytherapy source) nearby the target tissue. The key device components include: • Intrauterine tandems (left angle, straight and right angle) • Endometrial applicator clamping unit with grub screws & allen wrench • Vaginal cylinder with lever handle • Sterilization box • Cleaning caps	

Intended & Indications for Use Statement:	**Universal Endometrial Applicator Set**	
	Intended Use	**Indications for Use**
	The Universal Endometrial Applicator Set is intended for use when performing HDR or PDR brachytherapy.	The Universal Endometrial Applicator Set is indicated for use for treating cancer of the vagina, cervix, endometrium and uterus using HDR or PDR brachytherapy.

The purpose of this Traditional 510(k) submission is to provide details on how the new **Universal Endometrial Applicator Set** is substantially equivalent to Varian's **Endometrial Applicator Set** (K980576).

The subject device Indications for Use and Intended Use remain similar to the predicate device.

Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices are based on the following similar elements:

- Device design, technology to deliver a radiation source via a tandem to a prescribed treatment area and then to deliver brachytherapy treatment as the predicate device.

Significant Differences compared to the predicate device

(according to the 510(k) Decision-Making Flowchart (Appendix A) in FDA's guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]")

This submitted device has changed the device material from stainless steel to titanium and from polysulfone to PEEK. The predicate device cannot be used in a CT environment whereas this submitted device can be used in a CT environment. The predicate device offered one straight and two angled tandems while this submitted device offers one straight and three angled tandems. The predicate device is compatible with one afterloader model whereas this submitted device is compatible with three after-loader models. PDR capability is not available in the U.S. market. This submitted device labeling Warnings and Cautions are updated to account for the design changes from the predicate device. The submitted device is updated to include an MR determination. EtO gas sterilization and the sterilization plug are removed for this submitted device. Cleaning caps are added to this submitted device.

Performance Data

Verification and validation were conducted according to QSR §820.30 and ISO 13485:2016 design control requirements. Submission documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s.

Biocompatibility testing

The Universal Endometrial Applicator device biocompatibility evaluation was conducted in accordance with the FDA Guidance for Industry and FDA Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", June 2016 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The testing included the following test types:

• Cytotoxicity	• Sensitization	• Chemical characterization
• Irritation	• Pyrogenicity	• Toxicological Risk Assessment

The Universal Endometrial Applicator was tested as tissue contacting for a duration of greater than 24 hours and less than 30 days.

Cleaning and Sterilization

The Universal Endometrial Applicator device electrical safety testing complies with the applicable ANSI/AAMI, ASTM and ISO standards for device cleaning and sterilization validation.

Electrical Safety and Magnetic Resonance

The Universal Endometrial Applicator device electrical safety testing complies with the applicable ANSI/AAMI 60601-1 and IEC 60601-2 standards for safety as well as the applicable ASTM standards for the MR environment.

Varian Medical's Universal Endometrial Applicator Set is similar to the predicate device Indications for Use. Compared to the predicate device, the basic operation and technological characteristics are substantially the same.

Verification testing was performed to demonstrate that the performance and functionality of the **Universal Endometrial Applicator Set** meets the design input requirements. Validation testing was performed on production equivalent devices, under clinically representative conditions by qualified personnel. International standards were incorporated into the device design and development.

No clinical tests have been included in this pre-market submission.

Standards Conformance

The subject device conforms in whole or in part with the following standards:

- ISO 14971:2019
- AAMI 11737-1:2018
- ANSI AAMI ST98:2022
- ASTM F67-13:2017
- ISO 17664-1:2021
- ISO/TS 17665-2:2009
- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-10:2010
- ISO 10993-12:2021
- ISO 10993-18:2020
- AAMI TIR-12:2020
- ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) + A1 2012
- IEC 62366-1:2015 +A1:2020
- ASTM F2503-20
- ASTM F2182-11a
- ISO 15223-1:2021
- ANSI/AAMI ST79:2017 & 2020 Amnd A1, A2, A3, A4 (Consol. Text)
- ASTM F3208-20
- ISO 11607-1:2020
- ISO 17665-1:2006/(R)2013
- TS 21726:2019
- ISO 10993-2:2006
- ISO 10993-6:2016
- ISO 10993-11:2017
- ISO 10993-17:2002
- ISO 10993-23:2021
- AAMI TIR-30: 2011
- IEC 60601-2-17:2013
- ASTM F2052-15
- ASTM F2119-07R2013
- ASTM F2213-06

The subject device also complies with the following non-FDA recognized standards:

- ISO 13485:2016

Conclusion

The non-clinical test data for the **Universal Endometrial Applicator Set** supports the safety of the device. Verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Varian considers the **Universal Endometrial Applicator Set** to be as safe and effective as the predicate device.