Varian Medical Systems, Inc.
% Mr. Peter Coronado
Sr. Director, Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

August 17, 2020

Re: K193240
Trade/Device Name: Universal Cylinder Applicator Family
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ
Dated: July 17, 2020
Received: July 20, 2020

Dear Mr. Coronado:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193240

Device Name
Universal Cylinder Applicator Family

Indications for Use *(Describe)*

The Universal Segmented Cylinder Applicator Set and Universal Stump Applicator Set are intended for cancer treatment of the vagina, vaginal stump and rectum using HDR or PDR brachytherapy.
The Universal Cervix Probe Sets in combination with the Universal Segmented Cylinder Applicator Set and the Universal Stump Applicator Set are intended for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using HDR or PDR brachytherapy.
The Universal Titanium Cervix Probe Sets in combination with the Universal Segmented Cylinder Applicator Set and the Universal Stump Applicator Set are intended for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The Universal Multi-Channel Cylinder Set is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium and rectum using HDR or PDR brachytherapy.
The Universal Cervix Probe Sets in combination with the Universal Multi-Channel Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.
The Universal Titanium Cervix Probe Sets in combination with the Universal Multi-Channel Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The Universal Interstitial Cylinder Set is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using intracavitary and interstitial HDR or PDR brachytherapy.
The Universal Cervix Probe Sets in combination with the Universal Interstitial Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.
The Universal Titanium Cervix Probe Sets in combination with the Universal Interstitial Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium 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.

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K193240

Premarket Notification: 510(k) Summary

510(k) Submission for Universal Cylinder Applicator Family

The following information is provided as required by 21 CFR 807.92.

SUBMITTER

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto, CA 94304

Contact Person: Peter J. Coronado
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Phone: 650-424-6320 | Fax: 650-646-9200
submissions.support@varian.com

Date Prepared: 22 November 2019

DEVICE

Device Name: Universal Cylinder Applicator Family

Common/Usual Name: Universal Cylinder Applicator Family

Product Code and Classification: Remote controlled radionuclide applicator system
JAQ | 21 CFR 892.5700 | Class II

PREDICATE DEVICE

K172611 - Universal Cylinder Applicator Family

No reference devices were used in this submission.

DEVICE DESCRIPTION

The Universal Cylinder Applicator Family (UCAF) is designed to be used with Varian afterloaders (GammaMedplus, VariSource, and Bravos) to deliver high dose rate (HDR) and pulsed-dose-rate (PDR) intracavity and interstitial brachytherapy treatments for gynaecological and rectal applications.

INDICATIONS FOR USE

The **Universal Segmented Cylinder Applicator Set** and **Universal Stump Applicator Set** are intended for cancer treatment of the vagina, vaginal stump and rectum using HDR or PDR brachytherapy.

The Universal Cervix Probe Sets in combination with the Universal Segmented Cylinder Applicator Set and the

Universal Stump Applicator Set are intended for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The Universal Titanium Cervix Probe Sets in combination with the Universal Segmented Cylinder Applicator Set and the Universal Stump Applicator Set are intended for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The **Universal Multi-Channel Cylinder Set** is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium and rectum using HDR or PDR brachytherapy.

The Universal Cervix Probe Sets in combination with the Universal Multi-Channel Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The Universal Titanium Cervix Probe Sets in combination with the Universal Multi-Channel Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The **Universal Interstitial Cylinder Set** is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using intracavitary and interstitial HDR or PDR brachytherapy.

The Universal Cervix Probe Sets in combination with the Universal Interstitial Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The Universal Titanium Cervix Probe Sets in combination with the Universal Interstitial Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The new device, referred to as the "subject device" throughout this submission, is the Universal Cylinder Applicator Family with added Universal Multi-Channel Cylinder (UMC) and Universal Interstitial Cylinder (UIC) Applicator Sets.

At a high level, both the applicators of the predicate device and the applicators added in the subject device are based on the same technological characteristics:

- All UCAF applicators and probes are designed for use with a Varian afterloader to deliver HDR and PDR brachytherapy for gynaecological and rectal cases.
- All UCAF applicators are used in the same CT and MR environment, and with the same cervix probes.

The following technological differences exist between the applicators of the subject and the predicate devices:

- With the addition of UIC applicators, UCAF can be used for intracavity and interstitial brachytherapy.
- UMC and UIC applicators have multiple peripheral channels that allow for asymmetric dose shaping to improve target volume coverage while reducing dose to organs at risk.
- All UCAF applicators and probes are now compatible with Bravos afterloader. Further, 25-mm UMC and UIC applicators are compatible with Kelowna GYN template.
- UMC and UIC applicators are composed of PEEK, while predicate applicators are composed of PPSU.

PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation was conducted in accordance with the *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", as recognized by the FDA. The following testing was performed:

- Chemical characterization
- Cytotoxicity
- Sensitization
- Irritation (intracutaneous reactivity)
- Material mediated pyrogenicity

The UMC and UIC Applicator Sets are intended for continuous use for less than 30 days and are therefore categorized as a surface device in contact with mucosal membrane and prolonged contact duration.

CT compatibility and MRI safety testing

CT compatibility was evaluated, and MRI safety testing was conducted in accordance with the *Guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* as recognized by the FDA. The following testing was performed:

- Magnetically-induced displacement force
- Magnetically-induced torque
- RF-induced heating
- MRI image artifacts

Non-clinical bench testing

Verification and validation testing were conducted in accordance with the FDA Quality System Regulation 21 CFR 820, ISO 13485 – Quality Management System standard, ISO 14971 – Risk Management standard, and other FDA-recognized consensus standards listed below.

Testing has been performed to demonstrate that:

- the device functions correctly with the specified compatible afterloaders;
- the device can withstand the number of use cycles it will experience in its specified lifetime;
- the device enables the radioactive source to be located to the required accuracy;
- the device is constructed of materials that are not significantly affected by the radiation to which it is exposed during its specified lifetime;
- the device may be sterilized effectively;
- the device can be used and sterilized for the specified cycle limits;
- the positional accuracy of the source in the devices is adequate;
- the device is biocompatible as per ISO 10993 standards;
- the device can be used safely and effectively in CT environments;
- testing of the UMC and UIC sets in MRI environments has demonstrated they are safe to use under the conditions specified in the labelling.

Test results demonstrate conformance to applicable requirements and specifications.

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

Standards conformance

UMC and UIC Applicator Sets conform to the following FDA-recognized and non-recognized standards:

General:	Sterilization:	Biocompatibility:	MRI Safety:	Packaging:
EN ISO 13485:2016[1]	ISO 14161:2009	ISO 10993-1:2009	ASTM F2503-13	EN ISO 11607-1:2017
EN ISO 14971:2012	ANSI AAMI ST79:2017	ISO 10993-5:2009	ASTM F2052-15	ISTA 3A:2008
IEC 62366-1:2015	ISO 17665-1:2006	ISO 10993-6:2016	ASTM F2213-11[2]	ASTM D4332-13[2]
IEC 60601-1:2005, MOD	ISO TS 17665-2:2009	ISO 10993-10:2010	ASTM F2182-11a	ASTM D4169-09[2]
IEC 60601-2-17:2013	ISO 17664:2017	ISO 10993-11:2017	ASTM F2119-07	ASTM D4728-06[1]
ISO 15223-1:2016		ISO 10993-12:2012		ASTM D5276-98[1]
BS EN 1041:2008[1]		ISO 10993-17:2009[3]		
		ISO 10993-18:2005[1]		
		ANSI AAMI BE83:2006		

[1] *Not an FDA consensus standard.*
[2] *The Agency recognizes a more recent edition of the standard.*
[3] *The Agency recognizes an earlier edition of the standard.*

Argument for substantial equivalence to the predicate device

A subset of technological characteristics and features of the subject device is different from the predicate device. However, Varian considers these differences to be enhancements of the predicate.

The intended use of the added applicators is the same as the intended use of the applicators that are already a part of UCAF, and the indications for use of the added applicators are within the scope of indications of the predicate device. The principle of operation of the added applicator sets is the same as that of the existing UCAF applicators. Verification and validation demonstrate that the subject device is as safe and effective as the predicate.

Varian therefore believes that UCAF with added UMC and UIC applicator sets is substantially equivalent to the predicate device.

CONCLUSION

Since the predicate device was cleared based only on non-clinical testing, no animal or clinical studies were performed for the subject device. The non-clinical data supports the safety of the device, and verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. There were no remaining discrepancy reports (DRs) which could be classified as Safety or Customer Intolerable.

Therefore, Varian considers the Universal Cylinder Applicator Family with added Universal Multi-Channel Cylinder and Universal Interstitial Cylinder Applicator Sets to be safe and effective and perform at least as well as the predicate device.