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

March 21, 2018

Re: K172611
Trade/Device Name: Universal Cylinder Applicator Family
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 6, 2018
Received: March 7, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K172611

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.

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

Universal Cylinder Applicator Family

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA 94304 Contact Name: Peter J. Coronado Phone: 650/424.6320 Fax: 650/646.9200 Date: 30 August 2017
Proprietary Name:	Universal Cylinder Applicator Family
Classification Name:	Remote controlled radionuclide applicator system 21 CFR892.5700 Class II
Common/Usual Name:	Universal Segmented Cylinder Applicator Set Universal Stump Applicator Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets
Predicate Devices:	K160516 - Universal Cylinder Applicator Family
Indications for Use:	The Universal Segmented Cylinder Applicator Set and Universal Stump Applicator Set are indicated for use 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 indicated for use 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 indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using HDR or PDR brachytherapy.

Device Description:

The applicator sets in this submission are designed to be used with the GammaMed Plus afterloader series, VariSource 200 and iX afterloaders to deliver high dose rate (HDR) and pulsed-dose-rate (PDR) brachytherapy treatment for gynaecological and rectal applications. The intracavitary applicators will be used for the treatment of cancerous tumors, and are designed to be inserted into a body cavity.

Technological Characteristics:

Feature Comparison Chart	**Predicate Device:** Universal Cylinder Applicator Family (K160516)	**Subject Device:** Universal Cylinder Applicator Family
Sets within the Universal Cylinder Applicator Family (UCAF)	• Universal Segmented Cylinder Applicator Set • Universal Stump Applicator Set • Universal Cervix Probe Sets	• Universal Segmented Cylinder Applicator Set • Universal Stump Applicator Set • Universal Cervix Probe Sets • Universal Titanium Cervix Probe Sets
Compatible Afterloader	<u>All Sets:</u> GammaMed Plus series VariSource 200 and iX	<u>All Sets:</u> GammaMed Plus series VariSource 200 and iX
Design	<u>Universal Segmented Cylinder Applicator Set:</u> Cylinder Segment Dimension: diameters 20, 25, 30, 35, 40 mm; length 30 mm Front Segment: 1 front segment for vaginal wall and vaginal stump treatment Front Segment Dimension: diameter 20, 25, 30, 35, 40 mm; length 50 – 60 mm Guiding Tube & Applicator Probe: straight rigid ø 3.2 mm; length 200 and 250 mm <u>Universal Stump Applicator Set:</u> Cylinder Dimension: diameters 20, 25, 30, 35 mm; length 140 mm Applicator Probe Dimension: ø 3.2 mm; inner length 200 and 250 mm	<u>Universal Segmented Cylinder Applicator Set:</u> Cylinder Segment Dimension: diameters 20, 25, 30, 35, 40 mm; length 30 mm Front Segment: 1 front segment for vaginal wall and vaginal stump treatment Front Segment Dimension: diameter 20, 25, 30, 35, 40 mm; length 50 – 60 mm Guiding Tube & Applicator Probe: straight rigid ø 3.2 mm; length 200 and 250 mm <u>Universal Stump Applicator Set:</u> Cylinder Dimension: diameters 20, 25, 30, 35 mm; length 140 mm Applicator Probe Dimension: ø 3.2 mm; inner length 200 and 250 mm

Feature Comparison Chart	**Predicate Device:** Universal Cylinder Applicator Family (K160516)	**Subject Device:** Universal Cylinder Applicator Family
	<u>Universal Cervix Probe Sets:</u> Diameter: 6.3 mm Inner Length: 320 mm Cervix Length: 30, 40, 50, 60, 70, 80 mm Probe Tip Shapes: Straight or Curved with 15°, 30°	<u>Universal Cervix Probe Sets:</u> Diameter: 6.3 mm Inner Length: 320 mm Cervix Length: 30, 40, 50, 60, 70, 80 mm Probe Tip Shapes: Straight or Curved with 15°, 30° <u>Universal Titanium Cervix Probe Sets:</u> Diameter: 3 mm Inner Length: 320 mm Cervix Length: 30, 40, 50, 60, 70, 80 mm Probe Tip Shapes: Curved with 15°, 30°, or 45°
Packing	<u>All Sets:</u> Individual	<u>All Sets:</u> Individual
Sterility	<u>All Sets:</u> Provided non-sterile	<u>All Sets:</u> Provided non-sterile
Sterilization Method	<u>All Sets:</u> Steam sterilization 132 °C for 4 min 134 °C for 3 min 134 °C for 5 min	<u>All Sets:</u> Steam sterilization 132 °C for 4 min 134 °C for 3 min 134 °C for 5 min
Biocompatibility	<u>All Sets:</u> Full biocompatibility	<u>All Sets:</u> Full biocompatibility
Materials	<u>Universal Segmented Cylinder Applicator Set:</u> Cylinder: PPSU plastic white Guiding Tube & Applicator Probe: PEEK plastic natural, Titanium <u>Universal Stump Applicator Set:</u> Cylinder: PPSU plastic white Applicator Probe: PEEK plastic natural, Titanium <u>Universal Cervix Probe Sets:</u> PEEK plastic natural, FEP, Titanium	<u>Universal Segmented Cylinder Applicator Set:</u> Cylinder: PPSU plastic white Guiding Tube & Applicator Probe: PEEK plastic natural, Titanium <u>Universal Stump Applicator Set:</u> Cylinder: PPSU plastic white Applicator Probe: PEEK plastic natural, Titanium <u>Universal Cervix Probe Sets:</u> PEEK plastic natural, FEP, Titanium <u>Universal Titanium Cervix Applicator</u>

Feature Comparison Chart	**Predicate Device:** Universal Cylinder Applicator Family (K160516)	**Subject Device:** Universal Cylinder Applicator Family
		Sets: Titanium
Anatomical Sites	Universal Segmented Cylinder Applicator Set and Universal Stump Applicator Set: Vagina, vaginal stump and rectum Universal Cervix Probe Sets: Vagina, vaginal stump, cervix, uterus and endometrium	Universal Segmented Cylinder Applicator Set and Universal Stump Applicator Set: Vagina, vaginal stump and rectum Universal Cervix Probe Sets and Universal Titanium Cervix Probe Sets: Vagina, vaginal stump, cervix, uterus and endometrium
Compatibility w/ Environment & Other Devices	All Sets: CT compatible Universal Segmented Cylinder Applicator Set, Universal Stump Applicator Set, and Universal Cervix Probe Sets: MR conditional	All Sets: CT compatible Universal Segmented Cylinder Applicator Set, Universal Stump Applicator Set, and Universal Cervix Probe Sets: MR conditional Universal Titanium Cervix Probe Sets: MR Unsafe
Where Used	All Sets: Brachytherapy treatment room	All Sets: Brachytherapy treatment room

Non-Clinical Tests:	Bench Testing has been performed to demonstrate that… • the devices function correctly with the specified afterloaders • the devices can withstand the number of cycles of use they will experience in its lifetime • the devices enable the radioactive source to be located to the accuracy required • the devices are constructed of materials that are not significantly affected by the radiation to which they are exposed in the lifetime of the product • the devices may be sterilized effectively • the devices can be used and sterilized for the specified cycle limits • the positional accuracy of the source in the devices is adequate • the devices are biocompatible as per ISO 10933 standards • the devices can be used safely and effectively in CT environments Results of Bench Testing showed conformance to applicable requirements and specifications.
Clinical Tests:	No clinical tests have been included in this pre-market submission.
Conclusions:	All the tests that were performed met the applied pass criteria. Varian considers the devices to be safe and effective and to perform as well or better than the predicate.