DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

August 10, 2016

Re: K160516
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: June 20, 2016
Received: June 27, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160516

Device Name

Universal Cylinder Applicator Family

Indications for Use *(Describe)*

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.

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 CA94304 Contact Name: Peter J. Coronado Phone: 650/424.6320 Fax: 650/646.9200 Date: 5th February 2016
Proprietary Name:	Universal Cylinder Applicator Family
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	Universal Segmented Cylinder Applicator Set Universal Stump Applicator Set Universal Cervix Probe Sets
Predicate Devices:	K141490 Universal Cylinder Set.
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 gynecological 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.
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.

Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	DEVICE FEATURE/SPECIFICATION 510(K) ID # K141490 UNIVERSAL SEGMENTED CYLINDER APPLICATOR SET AND UNIVERSAL STUMP APPLICATOR SET	NAME AND VERSION UNIVERSAL SEGMENTED CYLINDER APPLICATOR SET AND UNIVERSAL STUMP APPLICATOR SET AND IN COMBINATION WITH UNIVERSAL CERVIX PROBE SETS
Compatible Afterloader	GammaMed Plus afterloader series VariSource 200 and iX afterloader	GammaMed Plus afterloader series VariSource 200 and iX afterloader
Intended use	The Universal Segmented Cylinder Applicator Set and the 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 Segmented Cylinder Applicator Set and the Universal Stump Applicator Set are intended 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 intended for use for cancer treatment of the vagina, vaginal stump, cervix, uterus and endometrium using HDR or PDR Brachytherapy
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Design	Segmented Cylinder: 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	Segmented Cylinder. 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 Universal Cervix Probe Sets: 6.3 mm diameter; inner length 320 mm; cervix length 30, 40, 50, 60, 70, 80 mm; straight, curved with 15° or 30°.

	Stump Applicator: Cylinder dimension: diameters 20, 25, 30, 35 mm; length 140 mm Applicator probe dimension: ø 3.2 mm; inner length 200 and 250 mm	Stump Applicator: Cylinder dimension: diameters 20, 25, 30, 35 mm; length 140 mm Applicator probe dimension: ø 3.2 mm; inner length 200 and 250 mm Universal Cervix Probe Sets: 6.3 mm diameter; inner length 320 mm; cervix length 30, 40, 50, 60, 70, 80 mm; straight, curved with 15° or 30°.
Materials	Segmented Cylinder: Cylinder: PPSU plastic white Guiding tube & applicator probe: PEEK plastic natural, Titanium Stump Applicator: Cylinder: PPSU plastic white Applicator probe: PEEK plastic natural, Titanium	Segmented Cylinder: Cylinder: PPSU plastic white Guiding tube & applicator probe: PEEK plastic natural, Titanium Universal Cervix Probe Sets: PEEK plastic natural, Titanium, FEP Stump Applicator: Cylinder: PPSU plastic white Applicator probe: PEEK plastic natural, Titanium Universal Cervix Probe Sets: PEEK plastic natural, Titanium, FEP
Packing	Individual	Individual
Sterility	Provided non-sterile	Provided non-sterile
Sterilization method	Steam sterilization 132 °C for 4 min 134 °C for 3 min 134 °C for 5 min	Steam sterilization 132 °C for 4 min 134 °C for 3 min 134 °C for 5 min
Biocompatibility	Full biocompatibility	Full biocompatibility
Anatomical sites .	Segmented Cylinder: Vaginal, rectum Stump Applicator: Vaginal, rectum	Segmented Cylinder & Cervix Probe Sets: Vaginal, vaginal stump, rectum, endometrium, cervix, uterus Stump Applicator / Cervix Probe Sets: Vaginal, rectum, vaginal stump, endometrium, cervix, uterus
Compatibility with the environment and other devices	Segmented Cylinder: CT compatible Stump Applicator: CT compatible	Segmented Cylinder & Cervix Probe Sets: CT compatible MR conditional Stump Applicator & Cervix Probe Sets: CT compatible MR conditional
Where used	Brachytherapy treatment room	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 number of times
- the positional accuracy of the source within the devices is adequate.
- the devices are biocompatible as per ISO10933 standards
- the devices can be used safely and effectively in CT environments
- testing of the Universal Cylinder Applicator Family in MRI environments has demonstrated they are safe to use under the conditions specified in the labelling.

Usability has been assessed to the requirements of IEC 62366:2007.

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