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, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

September 26, 2014

Re: K141490
Trade/Device Name: Universal Segmented Cylinder Applicator Set and Universal Stump Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: August 15, 2014
Received: August 18, 2014

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

Janine M. Morris
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)*
K141490

Device Name
GM11011100 - Universal Segmented Cylinder Applicator Set
GM11011160 - Universal Stump Applicator Set

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification [510(k)] Summary

GM11011100 Universal Segmented Cylinder Applicator Set

GM11011160 Universal Stump Applicator Set

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: 04 June 2014
Proprietary Name:	Universal Segmented Cylinder Applicator Set Universal Stump Applicator Set
Classification Name:	Remote controlled radionuclide applicator system 21 CFR 892.5700, Class II Product Code: JAQ
Common/Usual Name:	Remote controlled radionuclide applicator system
Predicate Devices:	K033371 Intracavitary Brachytherapy Applicators (11-00415 Segmented Cylinder Set, 11-00416 Stump Applicator 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.
Intended Use Statement	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.
Indications for Use Statement	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.

Technological Characteristics:

	Segmented Applicator Cylinder Set and Stump Applicator Set (K033371)	*Universal Segmented Cylinder Applicator Set and Universal Stump Applicator Set*
Compatible Afterloader	Varian Afterloader (GammaMed and VariSource)	GammaMed Plus afterloader series Varisource 200 and IX afterloader
Intended use	<u>11-00415 Segmented Cylinder Set</u> Segmented Cylinder Set is developed to treat cancer of the vagina and the vaginal stump. It is also suitable to treat rectal cancer. The applicator set is MR and CT compatible. The maximum implantation time for this applicator is 2 days. <u>11-00416 Stump Applicator Set</u> Stump Applicator Set is developed for post-operative irradiation of the vaginal stump. The flexible applicator probe has a connector made of titanium, so that position checks can be made using CT or MRI. The maximum implantation time for this applicator is 30 days.	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.
Indications for Use	The applicators will be used with the VariSource High Dose Rate Afterloaders to deliver brachytherapy treatment for gynecological and rectal applications. The applicators will be used in medical intracavitary for treatment of cancerous tumors.	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.
Design	<u>Segmented Cylinder</u>: Cylinder segment dimension: diameters 20, 25, 30, 35 mm; length 30 mm Front segment: 2 front segments for vaginal wall and vaginal stump treatment Front segment dimension: diameters 20, 25, 30, 35 mm; length 20 – 27.5 mm Guiding tube: straight ø 6.4 mm; length 228 mm Applicator probe: ø 3.2 mm; inner length 320 mm; flexible with blocking washer <u>Stump Applicator</u>: Cylinder dimension: diameters 20, 23, 26, 30, 35 mm; length 140 mm Applicator probe dimension: ø 3.2 mm; inner length 320 mm	<u>Segmented Cylinder:</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>Stump Applicator:</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

Materials	Segmented Cylinder: Cylinder: PPSU plastic white Guiding tube: PEEK plastic natural Applicator probe: FEP, Titanium Stump Applicator: Cylinder: PPSU plastic white Applicator probe: PVDF, Titanium	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
Packing	Individual	Individual
Sterility	Provided non-sterile	Provided non-sterile
Sterilization method	Steam sterilization 134 °C for 5 minutes 121 °C for 15 minutes	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	Segmented Cylinder: Vaginal, rectum Stump Applicator: Vaginal, rectum
Compatibility with the environment and other devices	Segmented Cylinder: CT compatible MR conditional Stump Applicator: CT compatible MR conditional	Segmented Cylinder: CT compatible MR conditional Stump Applicator: CT compatible MR conditional
Where used	Brachytherapy treatment room	Brachytherapy treatment room

Non Clinical Tests
Bench Testing has been performed to demonstrate that

- the device functions correctly with the specified afterloaders;
- the device can withstand the number of cycles of use that it will experience in its lifetime;
- the device enables the radioactive source to be located to the accuracy required,
- the device is constructed of materials that are not significantly affected by the radiation to which they are exposed in the lifetime of the product;
- the device may be sterilized effectively
- the device can be used and sterilized for the specified number of times
- the positional accuracy of the source within the applicator is adequate.

Usability was 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.