DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 7, 2015

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

Re: K151657
Trade/Device Name: Shielded Applicator Set-GM11004380, Cervical Stop-GM11000670
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: June 17, 2015
Received: June 19, 2015

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.
Acting 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)*
K151657

Device Name
GM11004380 - Shielded Applicator Set
GM11000670 - Cervical Stop

Indications for Use *(Describe)*
The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy.

The Cervical Stop is indicated for use with Varian metallic intrauterine tandems/probes to provide a physical stop for depth of insertion of these applicators within the uterus during 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

GM11004380 Shielded Applicator Set
GM11000670 Cervical Stop

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: 17 June 2015
Proprietary Name:	Shielded Applicator Set - GM11004380 Cervical Stop- GM11000670
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 (Primary predicate: GM11004380 – Shielded Applicator Set Secondary predicate: 1100404 – Cervix Applicator Set, Cervical Stopper)
Device Description:	The applicator set in this submission is designed to be used with all Varian afterloaders to deliver high dose rate (HDR) and pulsed-dose-rate (PDR) brachytherapy treatment for gynecological and rectal applications. The intracavitary applicator will be used for the treatment of cancerous tumors, and are designed to be inserted into a body cavity. The cervical stop is a stainless steel component that is placed on the applicator probe during HDR and PDR brachytherapy treatment of the uterus. It provides a physical stop for depth of insertion.
Intended Use Statement – Shielded Applicator Set	The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy.
Intended Use Statement – Cervical Stop	The Cervical Stop is indicated for use with Varian metallic intrauterine tandems/probes to provide a physical stop for depth of insertion of these applicators within the uterus during HDR or PDR brachytherapy.

Indications for Use Statement – Shielded Applicator Set	The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy.
Indications for Use Statement – Cervical Stop	The Cervical Stop is indicated for use with Varian metallic intrauterine tandems/probes to provide a physical stop for depth of insertion of these applicators within the uterus during HDR or PDR brachytherapy.

Technological Characteristics:

	Shielded Applicator Set (K033371)	*Modified Shielded Applicator Set*
Compatible Afterloaders	VariSource Afterloader Systems	VariSource iX™ VariSource 200™ GammaMedplus iX™ GammaMedplus™
Intended use	Shielded applicator is developed to treat cancer of the vagina or rectum where partial shielding is required. The max implantation time for this applicator is 2 days	The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy.
Indications for Use	The applicator will be used with the VariSource High Dose Rate Afterloaders to deliver brachytherapy treatment for gynecological and rectal applications. The applicator will be used in medical intracavitary for treatment of cancerous tumors.	The Shielded Applicator Set is intended for cancer treatment of the vagina, vaginal stump or rectum where partial shielding is required using HDR or PDR Brachytherapy.
Design	Cylinder: - Ø 20, 23, 26, 30, 35mm - length 140mm Applicator probe: - Ø 3.0mm, straight - Length 320mm Tungston Alloy Shielding: - 90°, 180° - Length 122.5mm Marking Screw (shielded) - 0°, 90°, 2 x 90°, 180°, 270° Clamping Nut for marking screw Clamping screw for probe, 3mm Plexiglass Filler Piece, 90° Yellow Cleaning Cap	Cylinder: - Ø 20, 23, 26, 30, 35mm - length 140mm Applicator probe: - Ø 3.0mm, straight - Length 320mm Tungston Alloy Shielding: - 90°, 180° - Length 122.5mm Marking Screw (shielded) - 0°, 90°, 2 x 90°, 180°, 270° Clamping Nut for marking screw Clamping screw for probe, 3mm Plexiglass Filler Piece, 90° Blue Cleaning Cap
Materials	- Shielding - Tungsten Alloy - Marking Screw, Clamping nut/Screw and applicator probe - Stainless Steel - Cylinders – PMMA - Cleaning cap- Silicone	- Shielding - Tungsten Alloy - Marking Screw, Clamping nut/Screw and applicator probe - Stainless Steel - Cylinders – PMMA - Cleaning cap- Silicone
Guide Tubes	- Source guide tube with locking mechanism for 320mm applicators GM plus - VariSource Transfer Guide Tubes	- Source guide tube with locking mechanism for 320mm applicators GM plus (K141336) - ClickFit transfer guide tube, set of 4 for VS 200 (K113766)

Optional accessories	- X-ray marker for 320mm applicators, 0.9mm, uncoded, GammaMedPlus - X-ray marker probe, for 320mm applicators, uncoded, GammaMed 12i(t) - VariSource X-ray marker wire - Leak stop button - VariSource Ruler - Flexible fixation device for gynecological applicators - Universal applicator clamping device (third party product) - Source guide tube support, GammaMed units only	- X-ray marker BV, up to 320 mm applicators, uncoded, GammaMedPlus - Leak stop button - Measurement Ruler - Measurement Marker Wire VS Measurement - Measurement Marker Clip - Flexible fixation device for gynecological applicators - Universal applicator clamping device (third party product) - Source guide tube support, GammaMed units only - Length gauge, GM plus - Cervical Stop - Allen Wrench
Packing	Individual	Individual
Sterility	Non sterile	Non sterile
Sterilization method	Steam sterilization (applicator probe, tungsten shielding and marking screws) EO Sterilization for PMMA parts Use of yellow Cleaning CAP (GM110003260)	Steam sterilization (applicator probe and marking screws) No sterilization of PMMA parts (use sterile medical condom) Use of dark blue Cleaning CAP (GM11010770)
Biocompatibility	Fully biocompatible only when used in combination with a sterile medical condom.	Fully biocompatible only when used in combination with a sterile medical condom.
Anatomical sites	The Shielded Applicator Set is used on female (vaginal and rectal) and male (rectal) patients.	The Shielded Applicator Set is used on female (vaginal and rectal) and male (rectal) patients.
Compatibility with the environment and other devices	N/A	Cervical Stop
Where used	The Shielded Applicator Set is intended to be used in a radiation therapy or radiation oncology department in a hospital environment.	The Shielded Applicator Set is intended to be used in a radiation therapy or radiation oncology department in a hospital environment.

Cervical Stop – GM11000670

	Cervical Stopper (part of K033371 – Cervix Applicator Set)	**Cervical Stop**
Compatible Applicators	Cervix Applicator Set	All Varian metallic intrauterine

		tandems/probes
Intended Use	The Cervical Stopper is indicated for use with the Cervix Applicator Set to provide a physical stop for depth of insertion of these applicators within the uterus during HDR or PDR brachytherapy.	The Cervical Stop is indicated for use with Varian metallic intrauterine tandems/probes to provide a physical stop for depth of insertion of these applicators within the uterus during HDR or PDR brachytherapy.
Indications for Use	The Cervical Stopper is indicated for use with the Cervix Applicator to provide a physical stop for depth of insertion of these applicators within the uterus during HDR or PDR brachytherapy.	The Cervical Stop is indicated for use with Varian metallic intrauterine tandems/probes to provide a physical stop for depth of insertion of these applicators within the uterus during HDR or PDR brachytherapy.
Material	PEEK/Titanium	PEEK/Titanium
Sterility	Non sterile	Non sterile
Reusable	Yes	Yes
Design	Ø 16mm flattened to 10mm Thickness 5.8mm	Ø 16mm flattened to 10mm Thickness 5.8mm

Non Clinical Tests

Bench Testing has been performed to demonstrate that

- the applicator functions correctly with the specified afterloaders;
- the devices can withstand the number of cycles of use that it will experience in its lifetime;
- the applicator enables 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 products;
- the device components may be sterilized effectively (as appropriate)
- the devices 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.