



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

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

December 17, 2015

Re: K151022

Trade/Device Name: Intraluminal Applicator Set GM11000620
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: November 13, 2015
Received: November 16, 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a grey shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151022

Device Name

Intraluminal Applicator Set GM11000620

Indications for Use (Describe)

The Intraluminal Applicator Set is indicated for use for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR 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

Intraluminal Applicator Set

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: 25 September 2015.

Proprietary Name: GM11000620 Intraluminal Applicator Set

Classification Name: Remote controlled radionuclide applicator system
21CFR892.5700
Class II

Common/Usual Name: GM11000620 Intraluminal Applicator Set

Predicate Devices: K983436.Gammamedplus High Dose Rate Remote Afterloading System.

Device Description: The Intraluminal Applicator Set is designed for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy. It is compatible with Varian GammaMedplus afterloaders and can be used in combination with the appropriate accessories.
The devices are intended to be used by trained and qualified personnel such as Radiation Oncologists, Physicians, Radiologists, Dosimetrists, Medical Physicists, and Nurses/MTRAs/Radiology Technicians/Radiographers in a hospital environment.

Indications for Use: The Intraluminal Applicator Set is indicated for use for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.

Technological Characteristics:

	<i>GM11000620 Intraluminal Applicator Set (as part of GammaMed afterloader-K983436).</i>	<i>GM11000620 Intraluminal Applicator Set</i>
Compatible Afterloader	GammaMed plus	GammaMed plus
Intended use	Covered by intended use of complete afterloader system in original submission: The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation.	The Intraluminal Applicator Set is intended for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.
Indications for Use	Covered by indication for use of complete afterloader system in original submission: The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation.	The Intraluminal Applicator Set is indicated for use for intraluminal brachytherapy treatments including endo-bronchial treatments and treatments on body sites such as the esophagus and the bile duct using HDR brachytherapy.
Design	<i>Set Components:</i>	<i>Set Components:</i>
	Bronchial catheter 5 Fr.(Ø 1.67mm), PA [MR Safe]	Bronchial catheter 5 Fr. (Ø 1.67mm), PA [MR Safe]
	Clamping adapter for 5 Fr. Catheter, stainless steel [MR Unsafe]	Clamping adapter for 5 Fr. Catheter, stainless steel [MR Unsafe]
	Guide tube Ø 2.8mm, L=900mm (FEP) [MR Safe]	Guide tube Ø 2.8mm, L=900mm (FEP) [MR Safe]
	Bite protector for intraluminal applicators, PBT [MR Safe]	Bite protector for intraluminal applicators, PPSU [MR Safe]
	Guide wire 0.0032" x 2600 mm, sterile, Stainless steel, PTFE coated (K082094) [MR Unsafe]	Guide wire 0.0032" x 2600 mm, sterile, Stainless steel, PTFE coated (K082094) [MR Unsafe]
	----	Monofil, PA [MR Safe]
	<i>Accessories:</i>	<i>Accessories:</i>

	GM11000620 Intraluminal Applicator Set (as part of GammaMed afterloader-K983436).	GM11000620 Intraluminal Applicator Set
	----	Tube catheter Ø 2.8mm (FEP) [MR Safe]
	----	Guide Tube Ø 4.5mm (FEP) [MR Safe]
	Length cutting gauge (stainless steel) [MR Unsafe]	Length cutting gauge (stainless steel) [MR Unsafe]
	X-ray marker (Nickel, Titanium, Aluminium, Tungsten, PEEK and PTFE coated) [MR Unsafe]	X-ray marker (Nickel, Titanium, Aluminium, Tungsten, PEEK and PTFE coated) [MR Unsafe]
	Length gauge (stainless steel) [MR Unsafe]	Length gauge (stainless steel) [MR Unsafe]
	Cleaning caps [MR Safe]	Cleaning caps [MR Safe]
	Tube Catheter, Ø 2.8mm (GammaMedplus) [MR Unsafe]	Tube Catheter, Ø 2.8mm (GammaMedplus) [MR Unsafe]
	Source guide tube support [MR Unsafe]	Source guide tube support [MR Unsafe]
Tube catheter	Tube catheter included as optional accessory	Tube catheter included as optional accessory
Materials	PA (Polyamide), FEP (Fluorinated Ethylene Propylene), Stainless Steel	PA (Polyamide), FEP (Fluorinated Ethylene Propylene), Stainless Steel PPSU (Polyphenylsulfone)
Packing	individual	individual
Sterility (Bronchial catheter and Monofil)	Supplied sterile – single use only	Supplied sterile – single use only
Sterilization method (Bronchial catheter and Monofil)	Gamma sterilization	Gamma sterilization
Sterilization method (Guide Tubes)	Steam sterilization – single use only	Steam sterilization – single use only
Sterilization method (Tube Catheter)	Steam sterilization up to 20 times	High level disinfection up to 20 times
Biocompatibility	Full biocompatibility	Full biocompatibility
Anatomical sites	Endo-bronchial treatments, esophagus (using a guide tube), and the bile duct.	Endo-bronchial treatments, esophagus (using a guide tube), and the bile duct.
Human factors	Controlled through Varian afterloaders	Controlled through Varian afterloaders

	<i>GM11000620 Intraluminal Applicator Set (as part of GammaMed afterloader-K983436).</i>	<i>GM11000620 Intraluminal Applicator Set</i>
Compatibility with the environment and other devices	CT and MR compatible	CT compatible and MR Safe (When MR Safe components as listed in Instructions for Use are used).
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