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

October 2, 2016

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

Re: K161576
Trade/Device Name: Esophagus Bougie Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 7, 2016
Received: September 9, 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)*

Device Name
Esophagus Bougie Set

Indications for Use *(Describe)*
The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used with a high dose rate afterloader.

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

GM11008880 Esophagus Bougie 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: June 6, 2016
Proprietary Name:	Esophagus Bougie Set - GM11008880
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:	K130251 Esophagus Bougie Set
Device Description:	The Varian Medical Esophagus Bougie is an HDR applicator designed to facilitate delivery of radiation to the Esophagus and has been modified to work with Varian Medical afterloaders. The product can be steam sterilized up to 20 times and has a maximum implantation time of 24 hours. The device does not contain any electronics or software. A high activity radioactive source is placed within the applicator which has previously been placed for a specified clinical purpose in a patient. The radioactive source (enclosed within the wire/cable) is driven via coupling catheters (Transfer Guide Tubes) from the Afterloader into the applicator within the patient. The length of time and position that the High Dose Rate source spends within the applicator is controlled in accordance with an Irradiation Treatment Prescription.
Intended Use Statement	The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used with a Varian high dose rate afterloader.
Indications for Use Statement	The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used with a Varian high dose rate afterloader.

Technological Characteristics:

	GM11008880 Esophagus Bougie Set (K130251)	*Modified Esophagus Bougie Set*
Intended use	The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used in conjunction with a high dose rate afterloader.	The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used with a high dose rate afterloader.
Indications for Use	The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used in conjunction with a high dose rate afterloader.	The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used with a high dose rate afterloader.
Compatible Afterloaders	GammaMed plus GammaMed 12i(t) VariSource	GammaMed plus VariSource
<u>Components and Dimensions:</u>		
Bougies	8, 10, 12 and 14 mm diameter	8, 10, 12 and 14 mm diameter
Tube catheter	3.2 mm diameter	3.2 mm diameter
Bite protector and fixation	For 8, 10, 12, and 14 mm bougie diameter	For 8, 10, 12, and 14 mm bougie diameter
Guidewire	0.032” x 2600mm (K082094)	0.032” x 2600mm (K082094)
Strap for bite protector bougie	(K955564)	(K955564)
<u>Materials:</u>		
Bougies	PVC (Polyvinylchloride)	PVC (Polyvinylchloride) **without DEHP**
Tube catheter	FEP (Fluorinated ethylene propylene)	FEP (Fluorinated ethylene propylene)
Bite protector and fixation	PPSU (Polyphenylsulfone)	PPSU (Polyphenylsulfone)
Guidewire	Stainless Steel PTFE coated	Stainless Steel PTFE coated
Packaging	Individual	Individual
Sterility (Bougie, tube catheter, Bite protector, clamping screws, threaded ring)	Non sterile	Non sterile

Sterility (Guidewire)	sterile, single use	sterile, single use
<u>Sterilization method:</u> Tube catheter Bougie Bite protector, clamping screws, threaded ring	 High Level disinfection up to 20 cycles Manual cleaning and high Level disinfection up to 20 cycles Steam sterilization up to 100 cycles	 High Level disinfection up to 20 cycles Manual cleaning and high Level disinfection up to 20 cycles Machine cleaning and thermal disinfection up to 20 cycles Steam sterilization up to 100 cycles Machine cleaning
Biocompatibility	Full biocompatibility Polymeric materials and stainless steel used.	Full biocompatibility Polymeric materials and stainless steel used.
Anatomical sites	Esophagus	Esophagus
Compatibility with the environment and other devices	CT compatible	CT compatible
Where used	Brachytherapy treatment room	Brachytherapy treatment room

Non Clinical Tests

Bench testing was performed to evaluate the efficacy of the automatic manual cleaning and disinfection process. Testing showed the test articles met the pre-defined acceptance criteria, thereby demonstrating the effectiveness of the cleaning and disinfection process plus the cleaning and disinfection agents according to DIN EN ISO 17664 (July 2004). Biocompatibility testing performed in accordance with ISO 10993-1 , 10993-5 and 10993-10 show the device is safe for bodily contact.

Per the FDA's Guidance document Deciding When to Submit a 510(k) for a Change to an Existing Device, only the formulation of this non-implant PVC material was changed. This plasticizer DEHP is considered a potentially dangerous substance and has been replaced with a safer alternative. The reformulated material was evaluated through design verification and testing. Non-clinical testing showed the test articles met the pre-defined acceptance criteria, thereby demonstrating the reformulated material did not impact device performance or biocompatibility.

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.