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

November 17, 2016

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

Re: K160045
Trade/Device Name: Heyman Packing Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: November 3, 2016
Received: November 4, 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)*

K160045

Device Name
Heyman Packing Applicator Set

Indications for Use *(Describe)*
Heyman Packing Applicator Set is indicated for use for treating endometrial cancer 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.

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

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510k Summary

510(k) Submission for Heyman Packing Applicator Set

As required by 21 CFR 807.92, Reference: FDA's Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (June 2014).

I. SUBMITTER

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E-110 Palo Alto CA 94304-1038
Contact Name:	Peter J. Coronado
Position:	Director, Regulatory Affairs
Phone:	1.650.424.6230
Fax:	1.650.646.9200
Email:	submissions.support@varian.com
Date Prepared:	Thursday January 07, 2016

II. DEVICE

Name of Device:	Heyman Packing Applicator Set
Common/Usual Name:	System, Applicator, Radionuclide, Remote-controlled
Regulation Name:	Remote controlled radionuclide applicator system (21 CFR 892.5700)
Regulatory Class:	Class II
Product Code:	JAQ

III. PREDICATE DEVICE

Name of Predicate:	GammaMed Plus High Dose Rate Remote Afterloading System
510k Number:	K983436

This predicate has not been subject to a design-related recall.
K152018 (Varian Cleaning Caps, Varian Leak Stop Buttons, Varian Leak Stop Channel Marker Sets) is used as a reference device for this submission.

IV. DEVICE DESCRIPTION

The Heyman Packing Applicator Set consists of various sized Heyman-capsules which may be connected to compatible brachytherapy afterloaders via guide tubes. The set also includes a number of associated accessories for sterilization (Cleaning Cap, Leak Stop Button, and Leak Stop Channel Marker Sets). The Heyman Packing Applicator Set is intended for cancer treatment of the endometrium using HDR or PDR brachytherapy. The Heyman Packing Applicator Set is an applicator for intracavitary Brachytherapy. The applicator acts to guide the radioactive source to the correct location or locations for treatment.

The device does not contain or consist of software/firmware. The device does not contain any biologics or drug components. The device has patient-contacting materials. The device is designed for repeated use. No parts of the system are provided sterile. The device can be steam sterilized with common parameters using pre-vacuum sterilization. This device is used on female patients.

The Heyman Packing Applicator Set is intended to be used in a healthcare or treatment facility by trained and qualified personnel.

The associated accessories include:

Product Number	Component List	Associated 510(k) Number
GM11005280	Heyman-capsule, 4mm diameter x 17.5mm length, with mandrin	This 510(k)
GM11005110	Heyman-capsule, 6mm diameter x 17.5mm length, with mandrin	
GM11005040	Heyman-capsule, 8mm diameter x 17.5mm length, with mandrin	
GM11010510	Leak Stop Channel Marker Set, 1 - 12	Cleared under K152018
GM11003810	Leak stop button, pack of 50	
GM11010770	Cleaning Cap, dark blue (pack of 25)	

V. INDICATIONS FOR USE

Indications for Use Statement: The Heyman Packing Applicator Set is indicated for cancer treatment of the endometrium using HDR or PDR brachytherapy.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are intended for use in the treatment of cancer through intracavitary brachytherapy. The subject device is based on a subset of applicator accessories from the predicate device.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Biocompatible Heyman-capsules of various sizes
- Application in intracavitary brachytherapy treatments
- Same anatomical treatment site/application
- Sterilized by user prior to use (and reuses)

The following main differences exist between the subject and predicate devices:

- Material change in the probe connect of the Heyman-capsule
- Validation of machine cleaning and the associated accessories
- Heyman capsules for the subject device are MR conditional
- Added VariSource afterloader compatibility

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Tests:

Biocompatibility Testing:

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. This included the following tests:

- Cytotoxicity
- Sensitization

- Irritation
- Systemic Toxicity
- Subacute Toxicity
- Implantation

The Heyman Packing Applicator Set is a surface device in contact with mucosal membrane and prolonged contact duration of 24 hours up to 30 days.

Sterilization Testing:
Sterilization testing was performed for the subject device was conducted to assess the effectiveness of the provided cleaning, disinfection, and sterilization procedures for the device. Furthermore, the components of the subject set were subjected to sterilization cycles up to the stated use life and evaluated for performance and any damage that might affect safety or effectiveness.

- Validation/Efficacy Testing of Cleaning, Disinfection, Sterilization Cycles
- Verification of the Suitability of Applicator Design and Material for the Stated Use Life and Reprocessing Cycles

Electrical Safety and Electromagnetic Compatibility (EMC):
This item is not applicable to the subject device. No electrical safety and electromagnetic compatibility tests have been included in this submission in support of the substantial equivalence determination.

Software Verification and Validation Testing:
This item is not applicable to the subject device; the device does not contain or consist of software/firmware. No software verification and validation testing has been included in this submission in support of the substantial equivalence determination.

Mechanical and Acoustic Testing:

- MRI Safety Tests and Analysis

- CT Compatibility Tests and Analysis
- Validation with the VariSource afterloader series

Animal Study / Clinical Tests:

No animal studies or clinical tests have been included in this submission in support of the substantial equivalence determination.

VIII. CONCLUSIONS

The results of the non-clinical tests support the safety and effectiveness of the device under the specified use conditions. Varian believes that the validation and verification testing demonstrates that the subject device performs comparably to the predicate device, meeting the intended use.