Varian Medical Systems, Inc.
Lynn Allman
Sr. Director, Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

August 30, 2024

Re: K241386
Trade/Device Name: Heyman Packing Applicator Set (GM11004580)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: July 29, 2024
Received: July 30, 2024

Dear Lynn Allman:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming

product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241386

Device Name
Heyman Packing Applicator Set (GM11004580)

Indications for Use *(Describe)*
The 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.

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Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for Heyman Packing Applicator Set (GM11004580)

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Lynn, Allman, PhD., Senior Director Regulatory Affairs
Phone: (650) 424-5369
E-mail: submissions.support@varian.com
Date Prepared: May 15th, 2024

II. Device Information

Proprietary Name: Heyman Packing Applicator Set (GM11004580)
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Heyman Packing Applicator Set (K160045)

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 an applicator for intracavitary Brachytherapy. Brachytherapy is a form of radiotherapy using Gamma rays from a radioactive source placed at locations close to or within a tumor or other treatment area to a predefined treatment plan. The treatment plan defines the positions and times for the source to ensure the correct dose for the treatment area. 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.

The Heyman Packing Applicator Set includes patients whose cancer can be treated using HDR or PDR brachytherapy, as determined by the prescribing physician. The Heyman Packing Applicator Set is intended to be used in a healthcare or treatment facility by trained and qualified personnel.

The key performance characteristics of this applicator set are as follows:

- Simulates the classic Heyman packing technique
- 4 mm, 6 mm, and 8 mm diameter capsules for optimal packing of the uterine cavity
- Mandrins stabilize the applicators during insertion
- CT Compatible
- MR Safe−without mandrins inserted
- Material is biocompatible for intracavitary use
- Leak stop channel markers allow for channel number coding
- Reusable and steam sterilizable
- Compatibility with all Varian afterloader systems
- Suitable for patient contact for a period of less than 30 days

V. Intended Use

The Heyman Packing Applicator Set is intended for use when performing HDR or PDR brachytherapy.

VI. Indications for Use

The Heyman Packing Applicator Set is indicated for use for treating endometrial cancer using HDR or PDR brachytherapy.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject Device to Predicate Device

Feature and/or Specification of new/modified device	Cleared Device Feature/Specification 510(k) ID # K160045 Heyman Packing Applicator Set	New / Modified Device Name Heyman Packing Applicator Set (GM11004580)	Comparison
Compatible Afterloader	GammaMed*plus* Afterloader series VariSource Afterloader series	GammaMed*plus* Afterloader series VariSource Afterloader Series BRAVOS Afterloader System	Device is compatible with the BRAVOS Afterloader System, it is just now being included in the labelling for completeness.
Intended use	The Heyman Packing Applicator Set is intended for cancer treatment of the endometrium.	The Heyman Packing Applicator Set is intended for use when performing HDR or PDR brachytherapy.	The intended use was amended to accurately reflect the use of the packing applicator set for general HDR or PDR brachytherapy procedures. The indications for use remain the same which ensures that the device is being used appropriately for the therapeutic indication for which it is intended. The indication for

			use statement has not changed and limits the clinical use of the set to endometrial cancer using HDR or PDR brachytherapy. Furthermore, the risk review for the Heyman Packing Applicator Set did not identify any new risks as a result of this change;
Indications for Use	The Heyman Packing Applicator Set is indicated for use for treating endometrial cancer using HDR or PDR brachytherapy.	No change	Same
Design	Heyman capsules: - 320 mm length - various capsule diameters of 4mm, 6mm and 8mm and length of 17.5 mm Mandrin: - 320 mm length	No change	Same
Materials	Heyman capsules: PEEK, Titanium Mandrin: Stainless Steel	Heyman capsules: PEEK Mandrin: Stainless Steel	This change has not identified any new or increased biocompatibility or safety concerns and does not impact the performance specifications of the subject device.
Packing	Individual	No change	Same
Sterility	Provided non-sterile	No change	Same
Sterilization method	Manual and Machine Cleaning, Disinfection, and Steam Sterilization	Manual or machine cleaning and disinfection. Steam sterilization with common parameters using Pre-vacuum sterilization.	These changes were cumulatively made as part of a process improvement initiative and is used to emphasize proper sterilization of the subject device. This does not impact the risk profile of the subject device.
Biocompatibility	Fully biocompatible	No change	Same

Anatomical sites	Endometrium	No change	Same
Compatibility with the environment and other devices	CT compatible MR-Conditional	CT compatible MR-Safe	This change was made to enhance the usability and flexibility of use in the intended population
Where used	Brachytherapy treatment room	No change	Same

VIII. Summary of Performance Testing (Non-Clinical Testing)

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

Biocompatibility Testing:
The compatibility of the skin-contact component material in the finished product meets the biocompatibility requirements. The Biological Evaluation Tests are in compliance with the standards of ISO 10993-1 and its applicable parts, "Biological Evaluation of Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process".

Magnetic Resonance Testing (MR):
MR Compatibility testing was completed, and documentation was provided to FDA in support of the substantial equivalence determination. The Heyman Packing Applicator Set is MR Safe and comply with the following MR standard:

- ASTM F2503-23 (2023 ED): Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Cleaning, Disinfection and Sterilization Testing:
Cleaning, disinfection and sterilization testing was conducted to demonstrate the device components may be sterilized effectively (as appropriate) and the device can be used and sterilized for the specified number of times.

A human factors validation study was conducted according to the standard IEC 62366 to verify that the device performs well as intended for the intended users, uses, and use environments.

Mechanical and Acoustic Testing:
The Heyman Packing Applicator Set has undergone formal design verification and design validation testing. Design verification and design validation testing demonstrates that the device performs as intended.

Design verification and design validation testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, and ISO 14971 Risk Management Standard.

Use of Consensus Standards:
The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

Standard / CS	Standard / CS Title
EN ISO 13485:2016	Quality management systems. Requirements for regulatory purposes
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN 62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
EN ISO 17664-1:2021	Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices
EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-2:2022	Biological evaluation of medical devices. – Part 2: Animal welfare requirements
EN ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices – part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2020+A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN 60601-1:2006/A1:2013	Medical Electrical Equipment Part 1- General Requirements For Safety and essential performance
EN 60601-2-17:2015	Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment

IX. Determination of Substantial Equivalence to the Predicate

The Heyman Packing Applicator Set was originally marketed as MR Conditional, but has now completed the testing to be classified as MR Safe.

The intended use was amended to accurately reflect the use of the packing applicator set for general HDR or PDR brachytherapy procedures. The indications for use remain the same which ensures that the device is being used appropriately for the therapeutic indication for which it is intended. The indication for use statement has not changed and limits the clinical use of the set to endometrial cancer using HDR or PDR brachytherapy. Furthermore, the risk review for the Heyman Packing Applicator Set did not identify any new risks as a result of this change.

There are no changes in the design or principle of operation of the devices.

Varian believes the major technological characteristics are substantially equivalent to the predicate device.

The results of verification and validation as well as conformance to relevant safety standards demonstrate that the device meets the safety and performance criteria. Varian considers the Heyman Packing Applicator Set to be substantially equivalent to the predicate device.