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

February 9, 2018

Re: K171631
Trade/Device Name: Standard Catheter Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: December 22, 2017
Received: January 3, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K171631

Device Name
Standard Catheter Set

Indications for Use *(Describe)*

The Standard Catheter Set is indicated for use to provide access to tumor sites for treatment of any case where high dose rate irradiation is an accepted clinical practice.

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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510k Summary

510(k) Submission for Standard Catheter 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 C260 Palo Alto CA 94304-1038
Contact Name:	Peter J. Coronado
Position:	Director, Regulatory Affairs
Phone:	1.650.424. 6320
Fax:	1.650.646.9200
Email:	submissions.support@varian.com
Date Prepared:	May 12, 2017

II. DEVICE

Name of Device:	**Standard Catheter 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

In this submission, some documents may reference the Standard Catheter Set by the common name Standard Catheters (AL1311XXXX).

III. PREDICATE DEVICE

Name of Predicate: Standard Catheters (as part of the ***Applicators for Varian Varisource Remote High Dose Rate Afterloader***).

510k Number: K952913

Please note that the required and optional accessories listed in Section 3.4 of the Device Description have been previously cleared under the 510(k) premarket notifications **K113766**, **K945383**, and **K952913**.

IV. DEVICE DESCRIPTION

The **Standard Catheter Set** (AL1311XXXX) is designed as an applicator for intraluminal Brachytherapy. The Standard Catheters are 4.7 French (1.6 mm in diameter) PTFE (Polytetrafluroethalene) catheters, which are supplied in nominal lengths of 100cm and 150cm with either a metal tip or plastic tip. The catheters can be readily inserted into small lumen. The metal tip catheter is sealed at the distal end with a small tungsten plug for easy visualization under fluoroscopy. The distal end of the plastic catheter is tightly sealed to prevent body fluids from entering the lumen or extension of the source wire beyond the tip. The catheters are shipped with a pin plug in the open end to keep the lumen clean and to keep the opening round. The applicator acts to guide the radioactive source to the correct location or locations for treatment.

The **Standard Catheter Set** is 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. The **Standard Catheter Set** is compatible with the Varian Afterloaders: VariSource iX™ and VariSource 200™.

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 supplied non-sterile and is intended for single use only.
This device is used on female and male patients.
The device can be steam sterilized with common parameters using pre-vacuum steam autoclave sterilization.

V. INDICATIONS FOR USE

Indications for Use Statement:

The Standard Catheter Set is indicated for use to provide access to tumor sites for treatment of any case where high dose rate irradiation is an accepted clinical practice.

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 intraluminal brachytherapy. The subject device is based on a subset of applicators from the predicate device, Standard Catheters (as part of the *K952913 Applicators for Varian Varisource Remote High Dose Rate Afterloader*).

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

- Biocompatible Standard Catheters
- Same design
- Application in intraluminal brachytherapy treatments
- Same anatomical treatment site/application

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

- Change and clarification to *Intended Use* and *Indications for Use* to apply specifically to Standard Catheter Set instead of the applicators for Varian Varisource Remote High Dose Rate Afterloader (K952913)
- The sterilization method for the standard catheter set is changed from ethylene oxide and plasma sterilization to steam sterilization only
- A change to the material of the plastic tipped catheter from Nylon to PTFE.

In addition to the changes listed above, other changes since the predicate device include the following:

- Verification of CT and MR compatibility

	CLEARED DEVICE FEATURE/SPECIFICATION	NEW / MODIFIED DEVICE
FEATURE AND/OR SPECIFICATION	PREDICATE DEVICE: **Standard Catheters** **(K952913 Applicators for Varian Varisource Remote High Dose Rate Afterloader)**	SUBJECT DEVICE: STANDARD CATHETER SET
Compatible Afterloader	• VariSource 200 and ID	• VariSource 200 and iX Series
Intended Use	*The VariSource applicators and accessories complete the VariSource system, and as such their intended use is the same as the parent VariSource device.* The Varian VariSource Remote High Dose Rate Afterloader system, including the applicators and accessories, is a device intended to be used by properly trained and licensed medical personnel to provide radiation brachytherapy with a high specific activity radioisotope source to reduce the exposure times required to achieve a prescribed dose. Remote operation of the afterloader eliminates the necessity of exposing medical personnel to radiation during hand loading or hand placement of radioactive sources on or within the body of a patient. The radioactive source is Iridium-192, encapsulated in the end of a wire stored in the afterloader and mechanically driven from it to a precisely described position for a specified dwell time during treatment. Between treatments the wire is retracted into the afterloader and the source end resides in a tungsten-shielded safe to limit personnel exposures to an acceptable, safe level. The Afterloader contains a radiation detector which signals whenever the source is not in the safe.	The Standard Catheter Set is intended to provide access to tumor sites for treatment of any case where high dose rate irradiation is an accepted clinical practice.

	CLEARED DEVICE FEATURE/SPECIFICATION	NEW / MODIFIED DEVICE
FEATURE AND/OR SPECIFICATION	PREDICATE DEVICE: **Standard Catheters** **(K952913 Applicators for Varian Varisource Remote High Dose Rate Afterloader)**	SUBJECT DEVICE: STANDARD CATHETER SET
Indications for Use	*The VariSource applicators and accessories complete the VariSource system, and as such their intended use is the same as the parent VariSource device. The statement of Indications for Use is the same as above.* The applicator, Standard Catheters, from the predicate device states the following indications in the **Instruction Manual**: The Standard Catheters are used to provide access to tumor sites for treatment of any case where high dose rate irradiation is an accepted clinical practice.	The Standard Catheter Set is indicated for use to provide access to tumor sites for treatment of any case where high dose rate irradiation is an accepted clinical practice.
Design	Catheters: Diameter: • 1.6 mm Length: • 100 cm • 150 cm	Catheters: Diameter: • 1.6 mm Length: • 100 cm • 150 cm
Material	• **Catheter Material :** PTFE • **Plastic Tipped Catheter :** Nylon • **Metal Tipped Catheter :** Tungsten coated with PTFE • **Metal Tipped Catheter Plug (distal end):** Tungsten • **Plastic and Metal Tipped Catheter Pin Plug (open end):** Delrin and stainless steel	• **Catheter Material :** PTFE • **Plastic Tipped Catheter :** PTFE • **Metal Tipped Catheter :** Tungsten coated with PTFE • **Metal Tipped Catheter Plug (distal end):** Tungsten • **Plastic and Metal Tipped Catheter Pin Plug (open end)::** Delrin and stainless steel

	CLEARED DEVICE FEATURE/SPECIFICATION	NEW / MODIFIED DEVICE
FEATURE AND/OR SPECIFICATION	PREDICATE DEVICE: Standard Catheters (K952913 Applicators for Varian Varisource Remote High Dose Rate Afterloader)	SUBJECT DEVICE: STANDARD CATHETER SET
Packing	• Individual	• Individual
Sterility	• Provided non-sterile	• Provided non-sterile
Sterilization method	• Ethylene Oxide • Plasma	• Steam autoclave
Biocompatibility	• Full biocompatibility	• Full biocompatibility
Anatomical sites	• Small lumen	• Small lumen
Compatibility with the environment and other devices	NA	• **CT compatible & MR conditional** (for plastic-tipped catheter only) • **CT compatible & MR unsafe** (for metal-tipped catheter)
Where used	• Brachytherapy treatment room	• Brachytherapy treatment room

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 10993-1, ‘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
- Subchronic Toxicity
- Genotoxicity
- Implantation

The Standard Catheters are intended for continuous use for less than 30 days of contact with patients. According to ISO 10993-1 the standard catheters are categorized as a medical device, external communicating device, Tissue/Bone communicating and prolonged contact duration (B).

Sterilization Testing:
Sterilization testing was performed for the subject device and 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.

- Steam Sterilization Validation Reports
- Validation/Efficacy Testing of Cleaning, Disinfection, Sterilization 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:

- CT Compatibility Test and Analysis
- Rationale MR Properties

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 as well as or better than the predicate device.