Varian Medical Systems, Inc
% Dr. Lynn Allman
Sr. Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO, CA 94304

February 1, 2024

Re: K232949
Trade/Device Name: Kelowna GYN and Crook Prostate Templates
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: December 20, 2023
Received: December 20, 2023

Dear Dr. 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)*
K232949

Device Name
Kelowna GYN and Crook Prostate Templates

Indications for Use *(Describe)*
The Kelowna GYN Templates are intended for interstitial brachytherapy treatments for gynecological and rectal/anal cancer using HDR or PDR brachytherapy.

The Crook Prostate Templates are intended for interstitial brachytherapy treatments for prostate 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

Kelowna GYN and Crook Prostate Templates

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: 20 September 2023

II. Device Information

Proprietary Name: Kelowna GYN and Crook Prostate Templates
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Kelowna GYN and Crook Prostate Templates (K162533)

IV. Device Description

The Kelowna GYN and Crook Prostate Templates are applicators for 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 applicators act to guide the radioactive source to the correct location or locations for treatment.

The key performance characteristics of Kelowna GYN and Crook Prostate Templates are as follows:

- Constructed of polyetheretherketone (PEEK), Titanium and stainless steel
- Used when performing HDR or PDR brachytherapy within a CT environment
- Accommodate the organization of interstitial implants; used with interstitial needles
- Provide for individual needle collet fixation
- Can be manually or machine cleaned; steam sterilizable
- Suitable for re-use
- Suitable for patient contact for a period of less than 30 days
- MR conditional and suitable for use during MR imaging for MRI systems of 1.5T or 3.0T if used with Varian interstitial plastic needles

V. Intended Use/Indications for Use

The Kelowna GYN Templates are intended for interstitial brachytherapy treatments for gynecological and rectal/anal cancer using HDR or PDR brachytherapy.

The Crook Prostate Templates are intended for interstitial brachytherapy treatments for prostate cancer using HDR or PDR brachytherapy.

VI. Comparison of Technological Characteristics with the Predicate Device

The major change addressed in this 510(k) is the change from MR unsafe to MR conditional when the templates are used with Varian interstitial plastic needles.

The change to the MR compatibility resulted in updates to 2 existing risk items. MR risks are now applicable resulting in updated warnings in the IFU.

Minor changes include:

- Addition of the BRAVOS afterloader system to the Compatible Afterloaders
- Addition of the 'Universal Multi-channel Cylinder Set' and 'Universal Interstitial Cylinder Set' to the Optional Accessories

One risk item was updated to include a warning within the IFU re: the use of third-party applicators and afterloaders.

The device comparison table below demonstrates the substantial equivalence of the subject Kelowna GYN and Crook Prostate Templates to the predicate Kelowna GYN and Crook Prostate Templates (K162533). The differences between the subject and predicate are indicated in yellow fill. The indications for use and the intended use of the subject device are the same as the predicate device.

Table 1. Comparison of Subject Device to Predicate Device

Feature and/or specification	Predicate Device: Kelowna GYN and Crook Prostate Templates K162533	Subject Device: Kelowna GYN and Crook Prostate Templates	Comparison
Intended Use/ Indications for Use	The Kelowna GYN Templates are intended for interstitial brachytherapy treatments for gynecological and rectal/anal cancer using HDR or PDR brachytherapy. The Crook Prostate Templates are intended for interstitial brachytherapy treatments for prostate cancer using HDR or PDR brachytherapy.	The Kelowna GYN Templates are intended for interstitial brachytherapy treatments for gynecological and rectal/anal cancer using HDR or PDR brachytherapy. The Crook Prostate Templates are intended for interstitial brachytherapy treatments for prostate cancer using HDR or PDR brachytherapy.	Same
Compatible Afterloader	GammaMedplus iX GammaMedplus VariSource iX VariSource 200	GammaMedplus iX GammaMedplus VariSource iX VariSource 200 Bravos Afterloader system	Now compatible with Bravos Afterloader System

Table 1. Comparison of Subject Device to Predicate Device

Feature and/or specification	Predicate Device: Kelowna GYN and Crook Prostate Templates K162533	Subject Device: Kelowna GYN and Crook Prostate Templates	Comparison
Optional Accessories	Universal Cylinder Applicator Family as cleared in K141490	Universal Cylinder Applicator Family as cleared in K193240	Substantially the same. Addition of Universal Multi-Channel Cylinder Set and Universal Interstitial Cylinder set as cleared in K193240
Compatibility with Imaging Environment	CT compatible MR Unsafe	CT compatible MR Conditional	MR compatibility has been updated to indicate MR conditional if used with Varian interstitial plastic needles

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

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

Biocompatibility Testing:

The biocompatibility evaluation for the subject device was conducted according to ISO 10993-1 'Biological Evaluation of a Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process." This includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subacute Toxicity

Sterilization Testing:

Sterilization testing 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 the safety or effectiveness.

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.

Magnetic Resonance Testing (MR):

MR Compatibility testing was completed, and documentation was provided to FDA in support of the substantial equivalence determination. The Kelowna GYN and Crook Prostate Templates are MR Conditional when used with Varian interstitial plastic needles and comply with the following MR standards:

- ASTM F2052-21 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

- ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance
- ASTM F2119-07 Standard Test Method for Evaluation of MR Artifacts from Passive Implants

Software Verification and Validation Testing:

This item is not applicable to the subject device. The devices do not contain or consist of software/firmware. No software verification and validation testing have been included in this submission in support of the substantial equivalence determination.

Mechanical and Acoustic Testing:

The Kelowna GYN and Crook Prostate Templates have undergone formal design verification and design validation testing. Design verification and design validation testing demonstrates that the Kelowna GYN and Crook Prostate Templates 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.

Table 2. Applicable Standards

Standard		
ANSI AAMI ST98:2022	ISO 10993-5	ASTM F2182-19e2
ANSI AAMI ST79:2017	ISO 10993-10	ASTM F2119-07
ISO 174664-1	ISO 10993-11	ASTM D4332-14
ISO 11138-1	ISO 10993-12	ISO 13485:2016
ISO 11607-1	ISO 10993-18	ISO 14971:2019
ISO 11737-2	ASTM F2052-21	ISO 15223-1:2021
ISO 17665-1	ASTM F2213-17	IEC 62366-1
ISO 10993-1		

No animal or clinical studies were conducted.

VIII. Determination of Substantial Equivalence to the Predicate Device

The Intended Use and indications for use are the same as the predicate device. Further, there are no changes in the materials or principle of operation of the devices. Varian believes the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness. 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 Kelowna GYN and Crook Prostate Templates to be as safe and effective as the predicate and to perform at least as well as the predicate device (K162533).