



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

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

August 31, 2017

Re: K162533

Trade/Device Name: Kelowna Gyn and Crook Prostate Templates  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote controlled radionuclide applicator system  
Regulatory Class: II  
Product Code: JAQ  
Dated: August 14, 2017  
Received: August 18, 2017

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue, semi-transparent "FDA" watermark. To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K162533

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.

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510k Summary

---

## 510(k) Submission for the Kelowna GYN and Crook Prostate Templates

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,  
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](mailto:submissions.support@varian.com)  
Date Prepared: August 25, 2016

### II. DEVICE

Name of Devices: Kelowna GYN and Crook Prostate Templates  
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

### IV. DEVICE DESCRIPTION

The Kelowna GYN and Crook Prostate Templates are applicator accessories 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 devices do not contain or consist of software/firmware. The devices do not contain any biologics or drug components. The devices have patient-contacting materials. The devices are designed for repeated use. No parts of the system are provided sterile. The devices can be steam sterilized with common parameters using pre-vacuum sterilization. These devices are used on both female and male patients.

The Kelowna GYN and Crook Prostate Templates are compatible with the following Varian Afterloaders: VariSource iX™, VariSource 200™, GammaMedplus iX™ and GammaMedplus™.

The Kelowna GYN and Crook Prostate Templates are CT compatible.

The devices are 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 associated components of the Kelowna GYN and Crook Prostate Templates include:

| Product Number | Component List                                                                                                                             | Associated 510(k) | Refer ISD                                |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------------------------------|
| GM11012200     | Kelowna GYN Template for 2.0 mm needles, including locking collets (pack of 25) and needle collet wrench                                   | This 510(k)       | Kelowna GYN and Crook Prostate Templates |
| GM11012210     | Kelowna GYN Template for 16 gauge (1.65 mm) needles, including locking collets (pack of 25) and needle collet wrench                       |                   |                                          |
| GM11012220     | Kelowna GYN Template for 17 gauge (1.47 mm) needles, including locking collets (pack of 25) and needle collet wrench                       |                   |                                          |
| GM11012230     | Crook Prostate Template for 2.0 mm needles, B-K labelling, including locking collets (pack of 25) and needle collet wrench                 |                   |                                          |
| GM11012240     | Crook Prostate Template for 17 gauge (1.47 mm) needles, B-K labelling, including locking collets (pack of 25) and needle collet wrench     |                   |                                          |
| GM11012250     | Crook Prostate Template for 2.0 mm needles, Siemens labelling, including locking collets (pack of 25) and needle collet wrench             |                   |                                          |
| GM11012260     | Crook Prostate Template for 17 gauge (1.47 mm) needles, Siemens labelling, including locking collets (pack of 25) and needle collet wrench |                   |                                          |

## V. INDICATIONS FOR USE

**Indications for Use Statement:** 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.

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both subject and predicate devices are intended for use in the treatment of cancer through interstitial brachytherapy.

|                                 | CLEARED DEVICE<br>FEATURE/SPECIFICATION                                                                                                                                                                                              | NEW / MODIFIED DEVICE                                                                                                                                      | NEW / MODIFIED DEVICE                                                                                      |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| FEATURE AND/OR<br>SPECIFICATION | <b>510(K) K983436 GAMMAMED PLUS HIGH DOSE RATE REMOTE AFTERLOADING SYSTEM (GM11004650 PROSTATE AND PERINEAL IMPLANT TEMPLATED SET IS LISTED IN ATTACHMENT B, PAGE 11)</b>                                                            | <b>KELOWNA GYN TEMPLATES</b>                                                                                                                               | <b>CROOK PROSTATE TEMPLATES</b>                                                                            |
| <b>Intended use</b>             | The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation. | The Kelowna GYN Templates are intended for interstitial brachytherapy treatments for gynecological and rectal/anal cancer using HDR and PDR brachytherapy. | The Crook Prostate Templates are intended for interstitial prostate cancer using HDR or PDR brachytherapy. |
| <b>Indication for use</b>       | The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation. | The Kelowna GYN Templates are intended for interstitial brachytherapy treatments for gynecological and rectal/anal cancer using HDR and PDR brachytherapy. | The Crook Prostate Templates are intended for interstitial prostate cancer using HDR or PDR brachytherapy. |

|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Applicator Design</b>      | <p>Various Plates (Templates) with 10 x 10mm hole geometry pattern;</p> <p>Cylinder, length 130mm, Ø 24.9mm;</p> <p>Needle: length 200mm, Ø1.65mm;</p> <p>Needle stopper/holder for 1.65mm needles;<br/>Pipe screw driver</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>Kelowna GYN Templates for 16 gauge, 17 gauge and Ø 2 mm needles</p> <p>Dosimetry based hole geometry pattern;</p> <p>Locking collets for fixation of needles;</p> <p>Needle collet wrench to securely affix the needles</p>                                                                                                                                                                                                 | <p>Crook Prostate Templates for 17 gauge and Ø 2 mm needles</p> <p>5 x 5 mm hole geometry pattern;</p> <p>Locking collets for fixation of needles;</p> <p>Needle collet wrench to securely affix the needles</p>                                                                                                                                                                                                                                                             |
| <b>Compatible Afterloader</b> | <p>GammaMed Plus Afterloader Series</p> <p>GammaMed 12i(t)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>GammaMed Plus Afterloader Series</p> <p>VariSource Afterloader Series</p>                                                                                                                                                                                                                                                                                                                                                   | <p>GammaMed Plus Afterloader Series</p> <p>VariSource Afterloader Series</p>                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Component List</b>         | <ul style="list-style-type: none"> <li>• Base plate for 1.65mm steel needles</li> <li>• Cover plate II without cylinder hole, with fixation screws</li> <li>• Cover plate III with centered cylinder hole with fixation screws</li> <li>• Cover plate IV with de-centered cylinder hole, with fixation screws</li> <li>• Cylinder, length 130mm, 24.9mm diameter</li> <li>• Base plate filling piece for needles</li> <li>• Cover plate filling piece for cylinder with fixation screws</li> <li>• Needle stopper for 1.56mm needles</li> <li>• Pipe screwdriver</li> <li>• Stainless Steel needle, 200mm, 1.65mm diameter</li> <li>• Sterilization plugs (pack of 25)</li> <li>• Cleaning caps, white (pack of 20)</li> </ul> | <ul style="list-style-type: none"> <li>• Kelowna GYN Template for Ø 2.0 mm needles, including locking collets (pack of 25) and needle collet wrench</li> <li>• Kelowna GYN Template for 16 gauge (1.65 mm) needles, including locking collets (pack of 25) and needle collet wrench</li> <li>• Kelowna GYN Template for 17 gauge (1.47 mm) needles, including locking collets (pack of 25) and needle collet wrench</li> </ul> | <ul style="list-style-type: none"> <li>• Crook Prostate Template for Ø 2.0 mm needles, B-K labelling, including locking collets (pack of 25) and needle collet wrench</li> <li>• Crook Prostate Template for 17 gauge (1.47 mm) needles, B-K labelling, including locking collets (pack of 25) and needle collet wrench</li> <li>• Crook Prostate Template for 2.0 mm needles, Siemens labelling, including locking collets (pack of 25) and needle collet wrench</li> </ul> |

|                                               |                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                               | <ul style="list-style-type: none"> <li>Channel marker clips, code 1-12</li> <li>Channel marker clips, coded 13-24</li> <li>Leak stop buttons, non-sterile, pack of 50</li> </ul>                                                                               |                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                          |
| <b>Materials</b>                              | Template: PPSU<br>Needle stopper: Stainless Steel<br>Screw Driver: Stainless Steel                                                                                                                                                                             | Template: PEEK<br>Locking collets: Titanium<br>Needle collet wrench: Stainless Steel                                                                                                                                                                                                                                                                                                 | Template: PEEK<br>Locking collets: Titanium<br>Needle collet wrench: Stainless Steel                                                                                                                                                                                                                                                     |
| <b>Packing</b>                                | Individual                                                                                                                                                                                                                                                     | Individual                                                                                                                                                                                                                                                                                                                                                                           | Individual                                                                                                                                                                                                                                                                                                                               |
| <b>Sterility</b>                              | Provided in non-sterile condition<br>Sterilized by user prior to use                                                                                                                                                                                           | Provided in non-sterile condition<br>Sterilized by user prior to use                                                                                                                                                                                                                                                                                                                 | Provided in non-sterile condition<br>Sterilized by user prior to use                                                                                                                                                                                                                                                                     |
| <b>Cleaning Method</b>                        | Manual cleaning                                                                                                                                                                                                                                                | Manual cleaning<br>Machine cleaning                                                                                                                                                                                                                                                                                                                                                  | Manual cleaning<br>Machine cleaning                                                                                                                                                                                                                                                                                                      |
| <b>Sterilization method</b>                   | Steam Sterilization                                                                                                                                                                                                                                            | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                  | Steam Sterilization                                                                                                                                                                                                                                                                                                                      |
| <b>Biocompatibility</b>                       | Fully biocompatible                                                                                                                                                                                                                                            | Fully biocompatible                                                                                                                                                                                                                                                                                                                                                                  | Fully biocompatible                                                                                                                                                                                                                                                                                                                      |
| <b>Anatomical sites</b>                       | Pelvic, vaginal, female urethral, cervical, prostatic and rectal                                                                                                                                                                                               | Pelvic                                                                                                                                                                                                                                                                                                                                                                               | Pelvic                                                                                                                                                                                                                                                                                                                                   |
| <b>Compatibility with Imaging Environment</b> | CT Compatible                                                                                                                                                                                                                                                  | CT compatible                                                                                                                                                                                                                                                                                                                                                                        | CT compatible                                                                                                                                                                                                                                                                                                                            |
| <b>Supporting Accessories</b>                 | Required: <ul style="list-style-type: none"> <li>interstitial accessory kit</li> </ul> Optional: <ul style="list-style-type: none"> <li>screws for cover plate</li> <li>source guide tube support</li> <li>16G stainless steel needle, 113mm,trocar</li> </ul> | Required: <ul style="list-style-type: none"> <li>Ø 2.0 mm Plastic Interstitial Needles (K141624)</li> <li>17G (1.47mm) Titanium and Stainless Steel Interstitial Needles (K160815)</li> <li>16G (1.65mm) Titanium and Stainless Steel Interstitial Needles (K160815)</li> </ul> Optional: <ul style="list-style-type: none"> <li>25mm diameter cylinders of the Universal</li> </ul> | Required: <ul style="list-style-type: none"> <li>Ø 2.0 mm Plastic Interstitial Needles (K141624)</li> <li>17 gauge (1.47mm) Titanium and Stainless Steel Interstitial Needles (K160815)</li> </ul> Optional: <ul style="list-style-type: none"> <li>Bard (Amertek) adapter</li> <li>Blue locking collets for Ø 2.0 mm needles</li> </ul> |

|                   |                                                                                                                    |                                                                                                                                                                                                                                                   |                                                                                                                           |
|-------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
|                   | point <ul style="list-style-type: none"> <li>Source guide tube with locking mechanism for 180mm needles</li> </ul> | Segmented Cylinder Applicator Set and Universal Stump Applicator Set <ul style="list-style-type: none"> <li>Blue locking collets for Ø 2.0 mm needles</li> <li>Locking collets for 16 G and 17 G needles</li> <li>Needle collet wrench</li> </ul> | <ul style="list-style-type: none"> <li>Locking collets for 16 G and 17 G needles</li> <li>Needle collet wrench</li> </ul> |
| <b>Where used</b> | Brachytherapy treatment room                                                                                       | Brachytherapy treatment room                                                                                                                                                                                                                      | Brachytherapy treatment room                                                                                              |

## VI. 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 devices 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
- System Toxicity
- Subacute Toxicity
- Implantation

According to ISO 10993-1 the components of the Kelowna GYN and Crook Prostate Templates are categorized as a medical device, surface device in contact with breached or compromised surfaces and prolonged contact duration (>24h to 30d). (B).

**Sterilization Testing:**

Sterilization testing for the subject devices were 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, and 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 devices. 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 devices; 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:**

- CT Compatibility Tests and Analysis
- Verification and Validation Testing for Applicator Design Specifications

**Declaration of Conformity:**

The following list are standards to which the subject devices declares conformity:

- AAMI TIR-12:2010
- AAMI TIR-30:2011
- ANSI/AAMI ST-79:2010/A2:2011/A3:2012/A4:2013 (R 2014)
- ANSI/AAMI ST-81:2004/(R)2010
- IEC 62366
- ISO 10993-1:2009

- ISO 10993-5:2009
- ISO 10993-10:2009
- ISO 17664:2004
- ISO 17665-1: 2006
- ISO 14937:2009/(R)2013

### **Animal Study / Clinical Tests:**

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

## **VII. 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 devices perform comparably to the predicate device, meeting the intended use.