Dear Peter J. 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. 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 located 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.

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 regulations.
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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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,

[Signature]

Robert A. 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

Device Name
GM Implant Tubes

Indications for Use (Describe)
The GM Implant Tubes is indicated for use for irradiation treatments which require a flexible source guiding lumen including treatments of the head, neck, tongue, bladder, gynecology and prostate using HDR or PDR brachytherapy.

The Length Cutting Gauge in its variable length is indicated for use to cut implant tube or breast applicator treatment channels to the correct treatment length.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@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 **GM Implant Tubes and Length Cutting Gauge**
The following information follows the format of 21 CFR 807.92.

I. SUBMITTER
Varian Medical Systems
3100 Hansen Way, m/s C260
Palo Alto CA 94304-1038

Contact Name: Peter J. Coronado
Phone: 1.650.424.6320
Fax: 1.650.646.9200
Email: submissions.support@varian.com
Date Prepared: August 18, 2017

II. DEVICE

Trade Name: #1: GM Implant Tubes
#2: Length Cutting Gauge

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
Please note: This predicate has not been subject to a design-related recall. The afterloader is cleared separately in K120993, which is capable in the delivery of High Dose Rate (HDR) and Pulsed Dose Rate (PDR) remote-controlled brachytherapy.

The Leak Stop Button and Leak Stop Channel Marker Sets which are included as a part of the GM Implant Tubes have been previously cleared under the 510(k) premarket notification, K152018. Some of the required and optional accessories have been previously cleared under the 510(k) premarket notifications K141336 GammaMedplus Source Guide Tubes and K983436 GammaMed Plus High Dose Rate Remote Afterloading System (GM Positioning Accessories).

IV. DEVICE DESCRIPTION

The GM Implant Tubes, listed in many of the submission document titles, is the family name covering the Flexible Interstitial Implant Tube Set and its required and optional components and the Length Cutting Gauge is an accessory component used with the Flexible Interstitial Implant Tube Set.

The Flexible Interstitial Implant Tube Set (GM11004680) from the GM Implant Tubes includes a variety of flexible implant tube lengths that create the optimal distance between the source and the layers of tissue to be treated. The implant tubes need to be cut down using the length cutting gauge to the required length. The set also includes a number of associated accessories for sterilization (K152018: Leak Stop Button, and Leak Stop Channel Marker Sets).

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GM11004680</td>
<td>Flexible Implant Tube Set</td>
</tr>
<tr>
<td>GM11008570</td>
<td>Flexible Implant Tubes, double leader, 530mm, sterile</td>
</tr>
<tr>
<td>GM11008580</td>
<td>Flexible Implant Tubes, blind-end, 530mm, sterile</td>
</tr>
<tr>
<td>GM11003200, GM11003210, GM11002700,</td>
<td>Implant Needle</td>
</tr>
<tr>
<td>GM11002930 and GM11006710-GM11006740</td>
<td></td>
</tr>
<tr>
<td>GM11003040 and GM11002820</td>
<td>Pushing device for implant needle</td>
</tr>
<tr>
<td>Product Number</td>
<td>Description</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>GM11003800</td>
<td>Universal fixation button, radiopaque, pack of 100, non-sterile</td>
</tr>
<tr>
<td>GM11003740, GM11003850, GM11003760, GM11003690, GM11003780, GM11003790</td>
<td>Clamping Buttons</td>
</tr>
</tbody>
</table>

Please note: The *Flexible Interstitial Implant Tube Set (GM11004680)* and the *flexible interstitial implant tubes* have the common name *Flexible Implant Tube Set (GM11004680)* and *flexible implant tubes*, respectively, which are stated in certain documents in this submission.

**Length Cutting Gauge:**

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GM11010000-10040 and GM11006670</td>
<td>Length Cutting Gauge</td>
</tr>
</tbody>
</table>

- **GM Implant Tubes** and **Length Cutting Gauge** do not contain or consist of software/firmware. The devices do not contain any biologics or drug components.
- **GM Implant Tubes** has patient-contacting materials.
- **GM Implant Tubes** contains some components that are designed for single use while other components are designed for repeated use.
  - The flexible interstitial implant tubes will be delivered in a sterile condition.
  - All other non-sterile components of the device can either be steam sterilized with common parameters using pre-vacuum sterilization or plasma sterilized.
- **GM Implant Tubes** is used on female and male patients.
- The **GM Implant Tubes** is compatible with the following Varian afterloaders: GammaMedplus iX™ and GammaMedplus™.
- **GM Implant Tubes** and **Length Cutting Gauge** are intended to be used in a healthcare or treatment facility by trained and qualified personnel.

More information is provided in the Device Description document.
V. INDICATIONS FOR USE

The intended use and indications for use were adapted to be applied specifically to the applicator instead of the afterloader system.

*The GM Implant Tubes is indicated for use for irradiation treatments which require a flexible source guiding lumen including treatments of the head, neck, tongue, bladder, gynecology and prostate using HDR or PDR Brachytherapy.*

We are also seeking clearance for the **Length Cutting Gauge** accessory with the following indications for use:

*The Length Cutting Gauge in its variable length is indicated for use to cut implant tube or breast applicator treatment channels to the correct treatment length.*

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 interstitial brachytherapy. The subject device is based on a subset of applicator accessories from the predicate device, **Flexible Interstitial Implant Set** from the GammaMed Plus High Dose Rate Remote Afterloading System (K983436).

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

- Application in interstitial brachytherapy treatments
- Similar anatomical treatment site/application

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

- Adaptation of intended use and indications for use to apply specifically to the applicator instead of generally to the afterloader system
- The device is capable of pulsed dose rate brachytherapy (PDR); the indications for use statement has been updated to include PDR brachytherapy as an indication
- The sterilization method for the clamping and fixation buttons is changed to plasma sterilization
• Addition of: **Implant Needle** (GM11003200, GM11003210, GM11002700, GM11002930, GM11006710, GM11006720, GM11006730, GM11006740)

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

• Certain components of the subject device have a MR safe claim
• Removed Application needle 1.25 mm diameter, 200 mm in length (GM11007930)
• Addition of **GM11008570 and GM11008580 Flexible Implant Tubes 530mm in length** and **GM11006670 Length cutting gauge 500mm in length** in subject device
• Validation of Manual and Machine Cleaning with the associated accessories
• Implant needle, pushing device for implant needle, and **length cutting gauge** can be machine and manual cleaned instead of manual cleaning
• Certain components of the subject device are CT compatible

Beside the changes listed above, there are no differences between the **Length cutting gauge** cleared in the predicate device – **Flexible Interstitial Implant Set (K983436)** and the current length cutting gauge device. However, we are adding a separate “indications for use” statement for the **Length cutting gauge** with this submission.

**VII. Summary of PERFORMANCE DATA**

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

**Non-Clinical Tests:**

**Biocompatibility Testing:**


This includes the tests for cytotoxicity, implantation, sensitization, and toxicity. *More information is provided in the Biocompatibility Safety Data*
Sterilization Testing:
Sterilization testing was performed for the subject devices 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.

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

CONCLUSION
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 as well as or better than the predicate device.