Varian Medical Systems, Inc.
c/o Peter J. Coronado
Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO, CA 94304

October 3, 2018

Re: K181903
Trade/Device Name: BRAVOS Afterloader Family: BRAVOS Afterloader System, Transfer Guide Tubes, and Length Assessment Device
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: August 20, 2018
Received: August 21, 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. 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 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,

Michael D. O'Hara For

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K181903

Device Name

BRAVOS Afterloader Family: BRAVOS Afterloader System, Transfer Guide Tubes, and Length Assessment Device

Indications for Use *(Describe)*

The BRAVOS Afterloader System is intended for use in the treatment of both benign and malignant disease or other conditions, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) brachytherapy.

The Transfer Guide Tubes are intended to connect between the BRAVOS Remote Afterloader system and its range of Applicators. This connection creates a conduit for the source cable to travel through and allows the radioactive isotopes to be positioned within the patient´s tumor site.

The Length Assessment Device is intended to allow the user to establish an approximate length of an unknown length channel prior to the afterloader performing definitive length verification.

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
*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."*

varian

**Varian Medical Systems**

3100 Hansen Way
Palo Alto, CA 94304

650.493.4000
800.544.4636

varian.com

# K181903 Premarket Notification 510(K) Summary

The following information is provided according to 21 CFR 807.92.

| | |
|---|---|
| **Submitter:** | Varian Medical Systems, Inc.<br>3100 Hansen Way Palo Alto, CA 94304<br><br>Contact Name: Peter J. Coronado<br>Phone: 650.424.6320<br>Fax: 650.646.9200<br>E-mail: submissions.support@varian.com<br><br>Date Prepared: October 2, 2018 |

| | | |
|---|---|---|
| **Trade/ Proprietary Names:** | BRAVOS Afterloader Family<br>• BRAVOS Afterloader System<br>• Transfer Guide Tubes (TGT)<br>• Length Assessment Device (LAD) | |
| | **BRAVOS Afterloader System**, Transfer Guide Tubes (TGT), Length Assessment Device (LAD) | |
| | **Classification Name**:<br>Remote controlled radionuclide applicator system, 21 CFR §892.5700<br><br>**Common/Usual Name:**<br>**Afterloader System**<br>Source Guide Tubes<br>Brachytherapy Accessory<br><br>**Regulatory Class:**<br>Class II<br><br>**Product Code:**<br>JAQ | **Predicate Devices:**<br><br>*(K120993)*<br>**GammaMedplus iX Series**<br><br>*(K141336)*<br>**GammaMedplus Source Guide Tubes**<br><br>(*K952913)*<br>**Applicators for Varian VariSource Remote HDR Afterloader**<br>➢ Accessory: *Measurement Ruler, Marker Wire & Clip Set* |

<table>
<tr><td rowspan="3">Device Description:</td><td colspan="2">BRAVOS Afterloader System<br>The BRAVOS Afterloader System is a computer controlled remote electro/mechanical system used for automatically placing a cable incorporating an irradiated iridium pellet (sealed source) internally or close by a malignant tumor or tumor bed in a practice known as Brachytherapy.</td></tr>
<tr><td colspan="2">Transfer Guide Tubes (TGT)<br>Transfer Guide Tubes (TGT) are Brachytherapy applicator accessories. They are designed to provide a path for the dummy and source cable from the BRAVOS Afterloader System to the Applicator. The applicator end of a Transfer Guide Tube can vary in design to accommodate a range of Applicators.</td></tr>
<tr><td colspan="2">Length Assessment Device (LAD)<br>The Length Assessment Device (LAD) is a Brachytherapy applicator accessory and is used to determine the approximate length of the inner lumen of the Transfer Guide Tubes (TGT) and applicator assembly.</td></tr>
<tr><td rowspan="11">Intended/ Indications For Use Statement:</td><td colspan="2">The indications for use and the intended use are substantially the same in the subject devices as for the predicate.</td></tr>
<tr><td colspan="2">BRAVOS Afterloader System</td></tr>
<tr><td>Intended Use</td><td>Indications for Use</td></tr>
<tr><td>The BRAVOS Afterloader System is intended for use in the treatment of both benign and malignant disease or other conditions, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) brachytherapy.</td><td>The Bravos Afterloader System is indicated for use in the treatment of both benign and malignant disease or other conditions, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) brachytherapy.</td></tr>
<tr><td colspan="2">Transfer Guide Tubes (TGT)</td></tr>
<tr><td>Intended Use</td><td>Indications for Use</td></tr>
<tr><td>The Transfer Guide Tubes are intended to connect between the BRAVOS Remote Afterloader system and its range of Applicators. This connection creates a conduit for the source cable to travel through and allows the radioactive isotopes to be positioned within the patient´s tumor site.</td><td>The Transfer Guide Tubes are intended to connect between the Bravos Remote Afterloader system and its range of applicators. This connection creates a conduit for the source cable to travel through and allows the radioactive isotopes to be positioned within the patient´s tumor site.</td></tr>
<tr><td colspan="2">Length Assessment Device (LAD)</td></tr>
<tr><td>Intended Use</td><td>Indications for Use</td></tr>
<tr><td>The Length Assessment Device is intended to allow the user to establish an approximate length of an unknown length channel prior to the afterloader performing definitive length verification.</td><td>The Length Assessment Device is intended to allow the user to establish an approximate length of an unknown length channel prior to the afterloader performing definitive length verification.</td></tr>
</table>

The three devices are used together during a diagnostic procedure and are bundled in this Traditional 510(k) submission so they can be addressed during one review; **BRAVOS Afterloader System**, Transfer Guide Tubes (TGT), and Length Assessment Device (LAD). The indications for use and the intended use are similar in the subject devices as for the predicate.

## Comparison of Technological Characteristscs with the Predicate Device

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

***BRAVOS Afterloader System***:

- Similar Design and Technology
- Similar Console Software (*subject device updated to version 2.0*)

Transfer Guide Tubes (TGT):

- Similar Design
- Composed of same materials
- Non-patient contacting (N/A Biocompatible)
- Provided Non-sterile

Length Assessment Device (LAD):

- Similar Compatibility with its respective Afterloader System
- Non-patient contacting (N/A Biocompatible)
- Provided Non-sterile

## Significant Difference

***BRAVOS Afterloader System***: The significant difference compared to the predicate devices are

- The *intended and indications for use* changed to exclude Pulsed Dose Rate (PDR) mode
- Updated Design and Technology of Remote-controlled Afterloader
- BRAVOS Control Software (*version 2.0*)
- BRAVOS CamScale Device
- BRAVOS Source Cable

The **BRAVOS Afterloader System** and its predicate are remote-controlled afterloading devices for brachytherapy. The systems both utilize a small, high activity Iridium-192 source that is encapsulated in a steel capsule, which is fixed to a stainless-steel cable and moves into applicator(s) or catheter(s) inserted into the patient.

Transfer Guide Tubes (TGT):

- Updated *Intended and Indications for Use* statements
- New Guide Tubes and lengths

| **Transfer Guide Tubes (TGT) for APPLICATORS** | |
|---|---|
| **Product Number** | **Description** |
| GM11010800 | Transfer Guide Tube for 320 mm applicators |
| GM11010810 | Coded Transfer Guide Tube Channel 1, for 320 mm applicators |
| GM11010820 | Coded Transfer Guide Tube Channel 2, for 320 mm applicators |
| GM11010830 | Coded Transfer Guide Tube Channel 3, for 320 mm applicators |
| GM11010840 | Transfer Guide Tube for 113 mm applicators |
| GM11010850 | Transfer Guide Tube for 200 mm applicators |
| GM11010860 | Transfer Guide Tube for 250 mm applicators |
| GM11010870 | Transfer Guide Tube, 1000 mm length for applicators |

| Transfer Guide Tubes (TGT) for CATHETERS | |
|---|---|
| **Product Number** | **Description** |
| GM11011860 | Transfer Guide Tube for 113 mm catheters |
| GM11011870 | Transfer Guide Tube for 200 mm catheters |
| GM11011880 | Transfer Guide Tube for 250 mm catheters |
| GM11011890 | Transfer Guide Tube for 320 mm catheters |
| GM11011910 | Transfer Guide Tube, 1000 mm length for catheters |
| **LUER Transfer Guide Tube (TGT)** | |
| **Product Number** | **Description** |
| GM11010880 | Luer Transfer Guide Tube for MammoSite (1500 mm treatment length) |
| ***Optional Accessory*** | |
| **Product Number** | **Description** |
| GM11001430 | Wall holder for source and transfer guide tubes |
| GM11001390 | Source and transfer guide tube support |

Length Assessment Device (LAD)**:**

- Updated *Intended and Indications for Use* statements
- New design
- New materials

| Length Assessment Device (LAD) | |
|---|---|
| **Product Number** | **Description** |
| GM11011800 | Length assessment device |

## Performance Data

Software verification and validation was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for **BRAVOS Afterloader System** was considered as a "major" level of concern.

Varian's BRAVOS Afterloader Family which consists of the **BRAVOS Afterloader System** and two accessories; Transfer Guide Tubes (TGT) and Length Assessment Device (LAD) are substantially equivalent to the predicate devices *K120993, K141336,* and *K952913* respectively. Compared with the predicate device, the basic operation and technological characteristics are substantially the same. The indications for use and the intended use for each device are substantially the same as the predicate.

No animal studies or clinical tests have been included in this pre-market submission.

Verification testing was performed to demonstrate that the performance and functionality of the new BRAVOS Afterloader Family met the initial design input requirements. Verification testing was performed to verify the integrity of any changes. Validation testing was performed on production equivalent devices, under clinically representative conditions by qualified personnel.

## Standards Conformance

The subject devices conform in whole or in part with the following standards:

- AAMI/ ANSI 60601-1: 2005
- IEC 60601-1-2: 2014
- IEC 60601-1-8:2006 + A1:2012
- IEC 60601-2-17:2013
- IEC 62304: 2006
- IEC 60601-1-6: 2013-10
- IEC 60825-1: 2007
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10: 2010
- EN ISO 10993-18:2009
- AAMI TIR-12:2010
- AAMI TIR-30: 2011
- EN ISO 17664:2004
- IEC 62366:2007/(R)2014
- EN ISO 14971:2012

The subject devices also comply with the following non-FDA recognized standard:

- EN ISO 13485:2016

## Conclusion

The non-clinical data for BRAVOS Afterloader Family supports the safety of the devices and the software verification and validation demonstrate that the subject devices should perform as intended in the specified use conditions. Varian therefore considers the BRAVOS Afterloader Family which consists of **BRAVOS Afterloader System** and two accessories; Transfer Guide Tubes (TGT) and Length Assessment Device (LAD) to be safe and effective and are substantially equivalent to the predicate.