



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

January 7, 2021

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

Dear Mr. Coronado:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 10/03/2018. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Sullivan, OHT7: Office of In Vitro Diagnostics and Radiological Health, (240) 402-4973, Julie.Sullivan@fda.hhs.gov.

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



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,

 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

Indications for Use

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.

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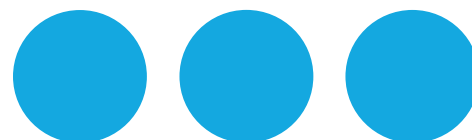
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**Varian Medical Systems**

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Palo Alto, CA 94304

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K181903 Premarket Notification 510(K) Summary

The following information is provided according to 21 CFR 807.92.

Submitter:	Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 E-mail: submissions.support@varian.com Date Prepared: October 2, 2018
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Trade/ Proprietary Names:	BRAVOS Afterloader Family • BRAVOS Afterloader System • Transfer Guide Tubes (TGT) • Length Assessment Device (LAD)	
	BRAVOS Afterloader System, Transfer Guide Tubes (TGT), Length Assessment Device (LAD)	
	Classification Name: Remote controlled radionuclide applicator system, 21 CFR §892.5700 Common/Usual Name: Afterloader System Source Guide Tubes Brachytherapy Accessory Regulatory Class: Class II Product Code: JAQ	Predicate Devices: (K120993) GammaMedplus iX Series (K141336) GammaMedplus Source Guide Tubes (K952913) Applicators for Varian VariSource Remote HDR Afterloader ➤ Accessory: <i>Measurement Ruler, Marker Wire & Clip Set</i>

Device Description:	<u>BRAVOS Afterloader System</u>	
	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.	
	<u>Transfer Guide Tubes (TGT)</u>	
	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.	
	<u>Length Assessment Device (LAD)</u>	
	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.	
Intended/Indications	<i>The indications for use and the intended use are <u>substantially the same</u> in the subject devices as for the predicate.</i>	
For Use Statement:	<u>BRAVOS Afterloader System</u>	
	Intended Use	Indications for Use
	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 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.
	<u>Transfer Guide Tubes (TGT)</u>	
	Intended Use	Indications for Use
	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 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.
	<u>Length Assessment Device (LAD)</u>	
	Intended Use	Indications for Use
	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.	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.
Source Activity	Subject Device: <u>BRAVOS Afterloader System</u>	Predicate Device: <u>GammaMedplus iX Series</u>
	Maximum shielding activity: 555 GBq / 15 Ci Maximum treatment activity: 555 GBq / 15 Ci	Maximum shielding activity: 555 GBq / 15 Ci Maximum treatment activity: 555 GBq / 15 Ci

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. The source activity was not changed since the predicate.

Comparison of Technological Characteristics 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.