Varian Medical Systems Inc.
% Peter Coronado
Senior Director
3100 Hansen Way, M/S/E-110
PALO ALTO CA 94304

Re: K221797
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: June 16, 2022
Received: June 21, 2022

Dear Peter 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/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 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 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,

for

Daniel M. Krainak, Ph.D.
Assistant Director
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)*
K221797

Device Name

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

Indications for Use *(Describe)*

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.

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)

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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: June 14, 2022

Trade/ Proprietary Names:	BRAVOS Afterloader Family (K191580) • 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 Device:** BRAVOS Afterloader Family (K191580) • **BRAVOS Afterloader System** • **Transfer Guide Tubes (TGT)** • **Length Assessment Device (LAD)**
Device Description:	**BRAVOS Afterloader System** The **BRAVOS Afterloader System** is a computer controlled remote electro/mechanical system used for brachytherapy. The system automatically moves a stainless-steel cable incorporating a small, high activity Iridium-192 pellet in a steel capsule (sealed source) into applicator(s) or catheter(s) inserted into the patient close by a malignant tumor or tumor bed.	

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<table>
<tr><td></td><td colspan="2">Transfer Guide Tubes (TGT)

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></td><td colspan="2">Length Assessment Device (LAD)

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 subject device's indications for use and the intended use have not changed since the predicate submission.</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>
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<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 purpose of this submission is to provide details on the updated **BRAVOS Afterloader System** which is a part of the Varian's BRAVOS Afterloader Family (K191580) for which we are claiming substantial equivalence.

There have been no updates to the accessories Transfer Guide Tubes (TGT) and Length Assessment Device (LAD) since the previous submission (K191580).

The subject device Indications for Use and Intended Use are identical to the predicate device.

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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:

- Same Intended Use and Indications for Use as Predicate device
- Similar Design and Technology as Predicate device
- Similar **Jaguar** Console Software (*subject device updated to version 2.1*)

Transfer Guide Tubes (TGT) and Length Assessment Device (LAD):

- Same as Predicate device (*no changes in the subject device*)

Significant Difference

BRAVOS Afterloader System: The significant differences compared to the predicate device are

- BRAVOS Control Software introduced new and modified risks plus risk control measures
- Warning statement added to the labeling

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

- Firmware, Control Software & Service Software:
  - Minor enhancements and bug fixes
- Afterloader:
  - Minor feature enhancements

Performance Data

Software verification and validation was conducted according to QSR §820.30 and ISO 13485:2016 design control requirements. Submission 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 determined to be a "major" level of concern.

Varian's BRAVOS Afterloader Family which consists of the **updated BRAVOS Afterloader System** is substantially equivalent to the predicate device *(K191580)*. Compared to the predicate device, the basic operation and technological characteristics are substantially the same. The above changes do not affect the intended use or indications for use of the **BRAVOS Afterloader System**.

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 **updated BRAVOS Afterloader System** meets 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.

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Standards Conformance

The subject device conforms in whole or in part with the following standards:

- IEC 60601-1-2: 2014 Edition 4.0
- IEC 60601-1-6: Edition 3.2 2020
- IEC 60601-1-8:2006 + A1:2012
- IEC 60601-2-17:2013
- IEC 62304: 2006 + A1:2015
- UL 2900-1:2017
- UL 2900-2-1:2017
- IEC 80001-1:2010
- IEC/TR 80001-2-2:2012
- ANSI / AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) + A1 2012
- IEC 62366-1:2015+A1:2020
- EN ISO 14971:2019
- ISO 15223-1:2021
- EN ISO 17664:2017
- AAMI TIR-12:2010
- AAMI TIR-30: 2011

The subject device also complies with the following non-FDA recognized standards:

- IEC 60825-1: 2014
- EN ISO 13485:2016

Conclusion

The non-clinical data for the **updated BRAVOS Afterloader System** from the BRAVOS Afterloader Family supports the safety of the device and the software verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Varian considers the **updated BRAVOS Afterloader System** from the BRAVOS Afterloader Family to be as safe and effective as the predicate device and substantially equivalent to the predicate device.