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

March 13, 2023

Re: K222775
Trade/Device Name: Aarhus Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: February 6, 2023
Received: February 8, 2023

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.03.13 14:47:17 -04'00'

Lora D. Weidner, 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)*
K222775

Device Name
Aarhus Applicator Set

Indications for Use *(Describe)*
The Aarhus Applicator Set is indicated for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy within a hospital CT or MRI environment.

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

Premarket Notification 510(k) Summary K222775

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: September 8, 2022

Trade/ Proprietary Names:	Aarhus Applicator Set	
	Aarhus Applicator Set	
	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:** 3D Interstitial Ring Applicator Set 60 & Set 90; Ring Applicator Set 45, Set 60, Set 90 (K150839)
Device Description:	**Aarhus Applicator Set** The **Aarhus Applicator Set** is an applicator for intracavitary/interstitial brachytherapy. The Applicator is inserted into the patient and connected to an afterloader. The applicator acts to guide the radioactive source from the afterloader to the correct location or locations for treatment. This combination places the remote-controlled radioisotope treatment source (brachytherapy source) nearby the target tissue.	

Intended/ Indications For Use Statement:	Aarhus Applicator Set	
	Intended Use	**Indications for Use**
	The Aarhus Applicator Set is intended for use when performing HDR or PDR brachytherapy within a CT and MRI environment.	The Aarhus Applicator Set is indicated for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy within a hospital CT or MRI environment.

The purpose of this Traditional 510(k) submission is to provide details on how the new **Aarhus Applicator Set** is similar to Varian's *3D Interstitial Ring Applicator Set 60 & Set 90; Ring Applicator Set 45, Set 60, Set 90* (K150839) for which we are claiming substantial equivalence.

The subject device Indications for Use is similar to the predicate device and Intended Use is similar to the predicate device.

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:

Aarhus Applicator Set:

- Similar Design and Technology as Predicate device

Significant Difference

Aarhus Applicator Set: The significant differences compared to the predicate device are

- The subject device Intended Use now includes a CT or MRI environment.
- The compatible afterloaders have been expanded to include the VariSource iX, 200 and BRAVOS models.
- The device material has been changed to PEEK-only.

Performance Data

Verification and validation were 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, Format for Traditional and Abbreviated 510(k)s.

Varian Medical's Aarhus Applicator Set is substantially equivalent to the predicate device *(*K150839*)*. Compared to the predicate device, the basic operation and technological characteristics are substantially the same.

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 Aarhus Applicator Set** meets the design input requirements. Validation testing was performed on production equivalent devices, under clinically representative conditions and by qualified personnel.

Standards Conformance

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

- ISO 14971:2019
- IEC 62366-1:2015 +A1:2020
- ISO 10993-1:2018
- ISO 10993-2:2006
- ISO 10993-5:2009
- ISO 10993-6:2016
- ISO 10993-10:2010
- ISO 10993-11:2017
- ISO 10993-12:2021
- ISO 10993-17:2002
- ISO 10993-18:2020
- ANSI AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text)
- IEC 60601-2-17:2013
- AAMI TIR-12:2010
- AAMI TIR-30: 2011
- ISO 15223-1:2021
- ISO 11607-1:2020
- ISO 11737-2:2019
- ISO 17664-1:2021
- ISO 17665-1:2006/(R)2013
- ISO/TS 17665-2:2009
- ASTM F2503-20
- ASTM F2052-15
- ASTM F2213-17
- ASTM F2182-19e2
- ASTM F2119-07
- ANSI / AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) + A1 2012
- ASTM D4332-13
- ASTM D4332-14
- ISTA 3A 2018

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

- ISO 13485:2016
- ISO 11138-3:2017
- ASTM D4332-13
- BS EN 1041:2008 +A1:2013

Conclusion

The non-clinical data for the **new Aarhus Applicator Set** supports the safety of the device and the verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Varian considers the new Aarhus Applicator Set to be as safe and effective, and substantially equivalent to the predicate device.