Varian Medical Systems, Inc.
Lynn Allman
Sr. Director, Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

January 10, 2025

Re: K241764
Trade/Device Name: Mould Probe MR Safe
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: June 18, 2024
Received: June 20, 2024

Dear Lynn Allman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
Assistant Director
Radiation Therapy Team
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241764

Device Name

Mould Probe MR Safe

Indications for Use *(Describe)*

The Mould Probe MR Safe is intended for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy.

IORT - Intraoperative Radiation Therapy

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.

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A Siemens Healthineers Company

Premarket Notification - 510(k) Summary

Mould Probe MR Safe

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Lynn Allman, PhD., Senior Director Regulatory Affairs
Phone: (650) 424-5369
E-mail: submissions.support@varian.com
Date Prepared: 18 June 2024

II. Device Information

Proprietary Name: Mould Probe MR Safe
Classification Name: Remote Controlled Radionucleotide Applicator System
Regulation Number: §892.5700
Product Code: JAQ

III. Predicate Device

Mould Applicator Set (K162615)

IV. Reference Device

Interstitial Needles (K073133)

V. Device Description

The Mould Probe MR Safe is a Brachytherapy applicator. Brachytherapy is a form of radiotherapy using Gamma rays from a radioactive source placed at locations close to or within a tumor or other treatment area to a predefined treatment plan. The treatment plan defines the positions and times for the source to ensure the correct dose for the treatment area. The applicator acts to guide the radioactive source to the correct location or locations for treatment.

The Mould Probe MR Safe is intended for HDR or PDR brachytherapy and the key performance characteristics are as follows:

- Suitable for intraoperative, intraluminal, and interstitial brachytherapy.
- Can be used for surface treatments in combination with the suitable Varian flap.
- Equipped with stabilizing mandrins for easy insertion.
- MR Safe, if used without mandrins.
- CT compatible, if used without mandrins.
- Elastomer material construction provides increased flexibility for easy placement as well as luminal rigidity, which prevents kinks.
- Steam sterilizable.
- Suitable for patient contact for up to 24 hours. The stainless steel mandrins are not intended to have patient contact.

VI. Intended Use/Indications for Use

The Mould Probe MR Safe is indicated for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy.
IORT = Intraoperative Radiation Therapy.

VII. Comparison of Technological Characteristics with the Predicate Device

The following are the major changes that are a part of this 510(k):

1. Change in material type of the probe connector material from titanium to PEEK. This changes the MR condition of Mould Probe from MR Conditional to MR Safe.
2. The clinical use of Mould probe MR Safe is contact for up to 24 hours. Full biocompatibility for Mould Probe MR Safe 1.8 mm has been tested for contact duration of 24 hours.
3. The Single use limitation has been removed from 1.8 mm Mould Probe MR Safe as the cleaning validation demonstrate it can be re-used for 25 cycles.
4. As part of the Mould Probe MR Safe, the Mandrin is considered a principal component rather than a separately cleared device.

Minor changes include:

- Addition of the BRAVOS Afterloader system to the Compatible Afterloaders.
- Availability of the Mould Probe MR Safe in kits with different quantities
  - Mould Probe MR Safe, 1.8 mm diameter x 320 mm, with mandrin, pack of 5
  - Mould Probe MR Safe, 1.8 mm diameter x 320 mm, with mandrin, pack of 10
  - Mould Probe MR Safe, 1.8 mm diameter x 320 mm, with mandrin, pack of 20
- Addition of machine cleaning process for Mould Probe MR Safe.
- Removal of expiration dating per assessment of lifetime limited factors used to establish expiration date in the prior 510(k).
- Removal of Mould Probe, ø 2.8 mm diameter x 320 mm
- The description of intended environment has been clarified for use in other suitable radiation oncology rooms as appropriate.

The device comparison table below demonstrates the substantial equivalence of the subject Mould Probe MR Safe to the predicate Mould Applicator Set (K162615). The differences between the subject and predicate are indicated in purple fill. Features which are adapted from the reference device are explained in Table 2 and appear in grey fill in the table below. The indications for use and the intended use of the subject device are the same as the predicate device.

Table 1 Comparison of Subject Device to Predicate Device

Features and/or specification	Predicate Device Mould Applicator Set K162615	Subject Device Mould Probe MR Safe	Comparison
Device name	Mould Applicator Set	Mould Probe MR Safe	Device name has changed to reflect change in included components.

Features and/or specification	Predicate Device Mould Applicator Set K162615	Subject Device Mould Probe MR Safe	Comparison
			As compared to the Mould Applicator Set, the Mould Probe MR Safe includes only the mould probe, probe connector and mandrin. See Design and Materials sections in this table.
Intended Use	The Mould Applicator Set is intended for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy. *IORT - Intraoperative Radiation Therapy*	The Mould Probe MR Safe is intended for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy. *IORT - Intraoperative Radiation Therapy*	No change.
Compatible Afterloader	GammaMedplus	GammaMedplus Afterloader series BRAVOS Afterloader System	Now also compatible with BRAVOS Afterloader system.
Design	Mould Probe Applicator Set Mould Probe Diameter: 1.8 or 2.8mm Length: 320 mm	Mould Probe MR Safe 1.8 mm Mould Probe Diameter:1.8mm Length: 320 mm Supplied with Mould probe MR safe, 1.8 mm diameter x 320 mm, with mandrin, pack of 5/10/20* *Refer to Packaging row in this table	No change in design for 1.8 mm Mould Probe The ø 2.8 mm diameter x 320 mm has been discontinued.
	Mandrin (GM11003100) [K073133]	Mandrin (GM11010470)	Substantially the same. Mould Probe MR Safe includes mandrin. Refer to Table 2 for comparison to reference device. The Mould Probe MR Safe now includes the mandrin as a principle component. As such, the mandrin will no longer use the existing clearance K073133, as the prior cleared mandrin component is

Features and/or specification	Predicate Device Mould Applicator Set K162615	Subject Device Mould Probe MR Safe	Comparison
			composed of Titanium (probe connector) and Stainless Steel (mandrin).
	Leak stop buttons, pack of 50 (GM11003810)[K152018] Cleaning Cap, dark blue (pack of 25) GM11010770 [K152018]	None	The other components of the applicator set are not included in the same packaging as a set and are now sold and cleared separately.
Materials	1.8mm Mould Probe: Polyamide (PA) 2.8mm Mould Probe: Fluorinated ethylene propylene (FEP)	Mould probe MR safe, 1.8 mm diameter x 320 mm: Polyamide (PA)	No change. The ø 2.8 mm size has been discontinued.
	Probe connector: Titanium Mandrin: Stainless steel	Probe connector: PEEK Victrex 450G Mandrin: Stainless steel	The connector material change to PEEK renders Mould Probe to be MR Safe. The material is diamagnetic, and it is non-conducting, has non-metallic properties and non-magnetic properties. Refer to Table 2 for further information.
Packaging	Individual	Individual and packs	Substantially the same. The product is available as individual and in packs with different quantities. Mould probe MR safe, 1.8 mm diameter x 320 mm, with Mandrin: Individual: • 1 Mould Probe with 1 Mandrin In packs: • pack of 5 • pack of 10 • pack of 20
Reprocessing, Sterility and Shelf life	1.8mm and 2.8mm Mould Probes: Manual Cleaning or Steam sterilization. 1.8mm Mould Probe is a single use product when steam sterilized.	1.8mm Mould Probe MR Safe: Manual Cleaning and Disinfection, Machine Cleaning and Disinfection, or Steam sterilization.	Substantially the same. The Single use limitation has been removed from 1.8 mm Mould probe as the cleaning validation demonstrate it can be re-used for 25 cycles.

Features and/or specification	Predicate Device Mould Applicator Set K162615	Subject Device Mould Probe MR Safe	Comparison
	Expiry date of 4 years for 1.8mm.	Removal of expiration date from 1.8mm Mould Probe MR Safe.	Additionally, 1.8mm can now be reprocessed through machine cleaning. The ø 2.8 mm size has been discontinued.
Biocompatibility	Full biocompatibility Max 24 hours contact for the 2.8mm Mould Probe. Max 7 days contact for 1.8mm Mould Probe.	Full biocompatibility Mould probe MR Safe is suitable for patient contact for up to 24 hours.	The clinical use of Mould probe MR Safe is suitable for patient contact for up to 24 hours. Full biocompatibility for Mould Probe 1.8 mm has been tested for contact duration of 24 hours. The 2.8 mm size has been discontinued.
Compatibility with the environment and other devices	MR conditional 1.5 and 3 T CT compatible	MR Safe, if used without Mandrins CT compatible, if used without Mandrins	Mould Probe is MR Safe and CT compatible after Mandrin removal, prior to entering the MR environment.
Intended environment	Brachytherapy treatment room.	Radiation therapy or radiation oncology department in a hospital environment.	Clarification of intended environment. Mould Probe MR Safe is to be used in a shielded, dedicated room/space for radiation therapy.

Table 2 Comparison of Subject Device to Reference Device

Features and/or specification	Reference Device Interstitial Needles K073133 (Compatible with Mould Probe Applicator Set)	Subject Device Mould Probe MR Safe	Comparison
Design	Mandrin (GM11003100) Stainless steel	Mandrin (GM11010470) Stainless steel	No change.
Materials	Probe connector: Titanium Mandrin: Stainless steel	Probe connector: PEEK Victrex 450G Mandrin: Stainless steel	The probe connector material change from Titanium to PEEK renders Mould Probe to be MR Safe.

VIII. Summary of Performance Testing (Non-Clinical Testing)

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

Biocompatibility Testing:

The biocompatibility evaluation for the subject device was conducted according to ISO 10993-1:2020: 'Biological Evaluation of a Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process" and the FDA Guidance: "Use of International Standard ISO 10993-1, Biological evaluation and testing within a risk management process". This includes the following tests:

- Cytotoxicity
- Irritation
- Delayed Type Hypersensitivity
- Material Mediated Pyrogens
- Acute Systemic Toxicity

Cleaning, Disinfection, Sterilization, Reprocessing:

Mould Probe MR Safe is supplied nonsterile. Sterilization testing for the subject device was conducted according to ANSI/AAMI, ASTM and ISO standards to assess the effectiveness of the provided cleaning, disinfection and sterilization procedures for the device.

Electrical Safety and Electromagnetic Compatibility (EMC):

A review report with applicable clauses of IEC 60601-1 and 60601-2-17 to Mould Probe MR Safe, along with evidence for successful implementation of the clauses has been conducted. The result of this review is that Mould Probe MR Safe meets the requirements of the above-mentioned clauses.

Magnetic Resonance Testing (MR):

Mould Probe MR Safe is made from non-metallic, non-magnetic materials. It is MR Safe after Mandrin removal and prior to entering the MR environment. Therefore, no tests according to ASTM F2052-21, ASTM F 2213-17, ASMT F2182-19E02 are required.

Software Verification and Validation Testing:

This item is not applicable to the subject device. The devices do not contain or consist of software/firmware. No software verification and validation testing have been included in this submission in support of the substantial equivalence determination.

Product verification and Validation testing

Mould Probe MR Safe has undergone formal design verification and validation testing; and it demonstrates that Mould Probe MR Safe performs as intended.
Testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, and ISO 14971 Risk Management Standard.

Use of Consensus Standards:

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

Table 3 List of Consensus Standards

Standard			
AAMI ANSI ST108:2023	ASTM F3208-20	ISO 10993-17	ISO 17665-1
ANSI AAMI ST79:2017	IEC 60601-2-17	ISO 10993-18	ISO 14971:2019
ANSI AAMI ST8:2013/(R) 2018	ISO 10993-1	ISO 10993-23	ASTM D4332-22
ANSI AAMI ST98:2022	ISO 10993-2	ISO 11138-1	
ANSI AAMI ISO TIR 17665-2	ISO 10993-5	ISO 11737-1	
ASTM D4169-22	ISO 10993-10	ISO 11737-2	
ASTM F2503-23	ISO 10993-11	ISO 17664-1	
ASTM F3293-18	ISO 10993-12	ISO 17664-2	

IX. Clinical Testing

No animal or clinical studies were conducted.

X. Determination of Substantial Equivalence to the Predicate Device

The intended use and indications for use are the same as the predicate device. There is no change to the principle operation of the device. Varian believes the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness. The results of verification and validation as well as conformance to relevant safety standards demonstrate that the device meets the safety and performance criteria. Varian considers Mould Probe MR Safe to be as safe and effective as the predicate and to perform at least as well as the predicate device (K162615).