January 5, 2022

Varian Medical Systems, Inc.
Peter Coronado
Senior Director Regulatory Affairs
9825 Spectrum Drive, Building 2, Suite 250
Austin, Texas 78717

Re: K211149
Trade/Device Name: Urethral Warming Catheter Kit
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 7, 2021
Received: December 8, 2021

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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)*
K211149

Device Name
Varian Urethral Warming Catheter Kit

Indications for Use *(Describe)*
The Varian Urethral Warming Catheter Kit, a set of disposable components used in conjunction with a warmer system, sterile water or saline, and peristaltic pump, is intended to transfer heat to urethra during urological cryosurgery with Varian CRYOCARE Systems.

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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PREMARKET NOTIFICATION

510(k) Summary

Urethral Warming Catheter Kit

The following information is provided as required by 21 CFR 807.92

I. Submitter's Information:

Name and Address:	Varian Medical Systems 9825 Spectrum Drive Building 2, Suite 250 Austin, TX 78717
Contact Name:	Mr. Peter J. Coronado, Senior Director Regulatory Affairs
Phone:	650-424-6320 | Fax: 650-646-9200
E-mail:	submissions.support@varian.com
Date Prepared:	December 7, 2021

II. Device Information:

Proprietary Name:	Urethral Warming Catheter Kit
Common/ Usual Name:	Cryosurgical Unit and accessories
Classification Name:	Cryosurgical unit and accessories
Regulation Number:	21 CFR 878.4350
Product Code	GEH

III. Predicate Device:

Urethral Warming System (K963970)

IV. Device Description:

The Urethral Warming Catheter Kit (CRYO-77) warms a patient's urethra during the cryoablation procedure by transferring heat through a catheter inserted within the urethra. The catheter contains fluid that is warmed using dry heat from an electrical heating unit (Warming unit) and circulated in a closed circuit using a peristaltic pump (circulating pump).

The Urethral Warming Catheter Kit contains the following:

- 22 french urethral balloon catheter
- Tubing
- Flow indicator
- Tubing clamp
- IV bag decanter
- Two luer connections
- Tube placement markers for pump
- Tube retainer

and is used in conjunction with a compatible fluid warming system and peristaltic pump. The fluid warming system supplies a steady flow of warm, sterile water or saline to the urethral catheter which transfers heat to the urethra during urological cryosurgery. The water or saline is circulated by a peristaltic pump from the catheter to the I.V. bag in a closed circuit.

The Urethral Warming Catheter Kit is recommended to use with 3M™ Ranger™ Model 245 Fluid

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Warmer System and 3M™ Ranger™ Fluid Warming Set, and a peristaltic pump meeting the following technical specifications:

- Pump mechanism- Roller-type peristaltic pump
- Compatible Pump head- Masterflex L/S® Easy-Load for use with 13, 14, 16, 25, 17, 18 tubing (07518-60, 77200-60, 77201-60 or similar)
- Operational nominal flow rate- 500 mL/min
- Minimum Pump RPM range 0-300RPM
- Maximum Continuous Pressure- 40PSIG
- Rated voltages 100V-240V; 50/60Hz
- IEC 61010 certified

The compatible fluid warming system and peristaltic pump are not owned or distributed by Varian. The system integration of Urethral Warming Catheter Kit with compatible accessories is the responsibility of end user.

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V. Indications for Use Statement:

The Varian Urethral Warming Catheter Kit, a set of disposable components used in conjunction with a warmer system, sterile water or saline, and peristaltic pump, is intended to transfer heat to urethra during urological cryosurgery with Varian **CRYOCARE** Systems.

VI. Comparison of Technological Characteristics with the Predicate Device:

At a high level, the subject device is similar to the predicate based on the following characteristics:

- Both the subject and predicate device have same indication for use to transfer heat to urethra during cryosurgery and have same urological clinical application
- The mechanism of action of urethral warming catheter is same in both subject and predicate device, the catheter in both devices uses heat transference to maintain the temperature of urethral tissue.

At a high level, the subject device differs from the predicate as a result of the following characteristics:

- The predicate device is a complete system consisting of a fluid warming system, peristaltic pump, IV stand, urethral warming catheter and tubing set. The subject device is a stand-alone device consisting of urethral warming catheter and tubing.
- Modification in indication for use of the subject device to include on-market available compatible accessories fluid warming system and peristaltic pump which deliver substantially equivalent tissue warming to that achieved by predicate device. The compatible accessories are not owned or distributed by Varian.
- Modification in sterilization method of urethral warming catheter
- Modification in packaging of urethral warming catheter
- Removal of heat exchanger cartridge from Urethral Catheter Kit
- Change in temperature range of fluid warming system
- Change in flow range of peristaltic pump

The table below includes a high-level comparison of the predicate and subject devices.

Table 1. – Predicate and Subject Device Comparison – Urethral Warming Catheter Kit

Feature and/ or Specification	Predicate Device Urethral Warming System (K963970)	Subject Device Urethral Warming Catheter Kit	Comparison between Subject and Predicate
Model Number	CRYO-60	CRYO- 77	NA
Indications for use	The Endocare Urethral Warming System is intended to transfer heat to urethral tissue during urological cryosurgery.	The Varian Urethral Warming Catheter Kit, a set of disposable components used in conjunction with a warmer system, sterile water or saline, and peristaltic pump, is intended to transfer heat to	The indication and clinical application remain the same. The differences in wording are due to the subject device's

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Table 1. – Predicate and Subject Device Comparison – Urethral Warming Catheter Kit

Feature and/ or Specification	Predicate Device Urethral Warming System (K963970)	Subject Device Urethral Warming Catheter Kit	Comparison between Subject and Predicate
		urethra during urological cryosurgery with Varian CRYOCARE Systems.	compatibility with on-market available fluid warming systems and peristaltic pumps rather than exclusive use with Endocare Urethral Warming System components - Alton Dean FW-537 warming system and adjustable RPM Rotary Peristaltic pump.
Product Configuration	• Fluid Warming System • Peristaltic Pump • IV Stand • Urethral Catheter Kit containing Urethral Warming Catheter, Tubing and Heat Exchanger Cassette	• Urethral Warming Catheter • Tubing	Predicate device is a complete system whereas the subject device is a stand-alone device.
Compatibility with Varian **CRYOCARE** Systems	• CRYO-CS System (K153489) • CRYO-204-V and CRYO-2017-V (K153489)	• CRYO-CS System (K153489) • CRYO-38T (K201588) • CRYO-204-V and CRYO-207-V (K153489, K201588)	Subject device will be additionally compatible with CRYO-38T
Fluid Warming System	Alton Dean FW-537	• 3M™ Ranger™ Model 245 Fluid Warmer System • 3M™ Ranger™ Fluid Warming Set	Subject device is compatible with fluid warming system and fluid warming set available on-market. The compatible accessories are not manufactured and distributed by Varian.
Temperature Range of Fluid Warmer	35-39°C	41-43°C	Difference in the temperature range of fluid warming system due to on-market available compatible accessories.
Pump	Adjustable RPM Rotary Peristaltic pump have the following technical specifications,	Peristaltic Pump available on-market meeting the following technical specifications,	Subject device is compatible with peristaltic pump available on-market. Peristaltic pump

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Table 1. – Predicate and Subject Device Comparison – Urethral Warming Catheter Kit

Feature and/ or Specification	Predicate Device Urethral Warming System (K963970)	Subject Device Urethral Warming Catheter Kit	Comparison between Subject and Predicate
	• **Pump mechanism-** Roller-type peristaltic pump • **Compatible Pump head-** Masterflex L/S® Easy-Load for use with 13, 14, 16, 25, 17, 18 tubing (77200-60)	• **Pump mechanism**- Roller-type peristaltic pump • **Compatible Pump head**- Masterflex L/S® Easy-Load for use with 13, 14, 16, 25, 17, 18 tubing (07518-60, 77200-60, 77201-60 or similar)	should meet the mentioned technical specifications to be compatible with subject device and 3M™ Ranger™ Fluid Warmer System. The compatible accessories are not manufactured and distributed by Varian
Flow Range of Peristaltic Pump	140-1700 mL/min	0 -1140 mL/min	Difference in the flow range of peristaltic pump is mitigated by providing nominal operational flow rate
Operational Flow rate	Not specified in K963970 submission	Nominal 500 mL/min, recommended by 3M™ Ranger™ Fluid Warmer System	Operational flow rate of predicate device is not specified in K963970 submission; however, the subject device is tested to perform at operational flow rate of nominal 500 mL/min, the specified fixed flow rate prevents over/under fluid circulation. The test result showed the subject device and its on-market available components (warmer and pump) installed together as a system perform equivalent to predicate cleared device and transfer the heat to the urethra equally during cryoablation procedure.
Mechanism of Action	Heat transfer	Heat transfer	Same
Urethral Warming	Double lumen closed circuit catheter	Double lumen closed circuit catheter	Same

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Table 1. – Predicate and Subject Device Comparison – Urethral Warming Catheter Kit

Feature and/ or Specification	Predicate Device Urethral Warming System (K963970)	Subject Device Urethral Warming Catheter Kit	Comparison between Subject and Predicate
Catheter Description			
Catheter Material	Polyurethane shaft with polyester balloon	Polyurethane shaft with polyester balloon	Same
Catheter Size	16-22 French	16-22 French	Same
Catheter Sterilization Method	Ethylene Oxide	Gamma	Subject device uses Gamma irradiation process
Packaging	Plastic film side and coated paper	Tray, Tyvek top, chipboard box	Subject uses Tray, Tyvek top, chipboard box

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VII. Performance Data (Non-Clinical Testing)

Design Verification and Design Validation testing were completed to demonstrate that the **Urethral Warming Catheter Kit** performs as intended and meets its essential performance specifications.

- Catheter to include flow indicator to ensure fluid is not impeded and flowing correctly through closed circuit system.
- Catheter is closed-circuit, free of fluid leaking or component separation
- Catheter is designed to dissipate cold thermal energy from the urethral mucosa

Bench testing included testing of the system, including:

- Biocompatibility Testing in accordance with ISO 10993 series of standards, including ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12
- Sterilization Validation in accordance with EN 556-1, ANSI/AAMI ST67, ISO 11137-1, ISO 11137-2, ISO 11737-1 and ISO 11737-2
- Usability Testing in accordance with IEC 62366-1 Annex C

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

VIII. Determination of Substantial Equivalence to the Predicate Device

A subset of technological characteristics and features of the subject device differs from the predicate device. These differences are all considered to be enhancements of the predicate, intended to configure urethral warming catheter as a stand-alone device compatible with on-market available accessories.

The indications for use are substantially the same as the predicate device. Further, there are no changes in the principle of operation of the devices. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes the data demonstrates that Varian Urethral Warming Catheter Kit is substantially equivalent to the predicate device, Endocare Urethral Warming System.

IX. Conclusion

The assessment following the outcomes observed in the performance testing determines that the Urethral Warming Catheter Kit conforms to the defined user needs and intended uses. Varian therefore considers the Urethral Warming Catheter Kit to be safe and effective and to perform at least as well as the predicate device.