March 28, 2023

Varian Medical Systems, Inc.
Peter Coronado
Director Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304-1038

Re: K230271
Trade/Device Name: ISOLIS Cryoprobe
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 31, 2023
Received: January 31, 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,

Jessica Carr -S

for 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)*
K230271

Device Name
ISOLIS cryoprobe

Indications for Use *(Describe)*

The ISOLIS cryoprobes, used with the Cryocare Systems, are intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The systems are designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

In addition, the systems are intended for use in the following indications:

General Surgery
• Destruction of warts or lesions
• Palliation of tumors of the oral cavity, rectum and skin
• Ablation of breast fibroadenomas
• Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions
Urology
• Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia
Gynecology
• Ablation of malignant neoplasia or benign dysplasia of the female genitalia
Oncology
• Ablation of cancerous or malignant tissue
• Ablation of benign tumors
• Palliative intervention
Neurology
• Freezing of nerve tissue in pain management/cryoanalgesia
Dermatology
• Ablation or freezing of skin cancers and other cutaneous disorders
Proctology
• Ablation of benign or malignant growths of the anus or rectum
• Ablation of hemorrhoids
Thoracic Surgery
• Ablation of cancerous lesions

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

ISOLIS™ Cryoprobe

The following information is provided as required by 21 CFR 807.92

I. Submitter's Information:

Name and Address:	Varian Medical Systems Inc.
	9825 Spectrum Drive, Building 2 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:	31st January 2023

II. Device Information:

Proprietary Name:	**ISOLIS™ Cryoprobe**
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:

CRYOCARE TOUCH™ System and Accessories: (K201588)

IV. Device Description:

The ISOLIS cryoprobe is a single use, disposable device designed for use with CryoCare® Systems. ISOLIS cryoprobes are designed to deliver cold temperatures for cryoablation using high-pressure argon gas circulated through the cryoprobe, followed by active thawing using helium gas. The refrigerative and warming capability is limited to the distal end of the probe shaft that is comprised of stainless steel and is designed with a pointed tip to facilitate cryoprobe insertion and placement.

ISOLIS Cryoprobe comprises 4 variants as listed below:

Model No	Description
PC-2.1E	Varian 2.1mm (14 G) ISOLIS™ Cryoprobe, 15cm Length, Ellipsoidal
PC-2.1S	Varian 2.1mm (14 G) ISOLIS™ Cryoprobe, 15cm Length, Spherical
PC-2.1EL	Varian 2.1mm (14 G) ISOLIS™ Cryoprobe, 20cm Length, Ellipsoidal
PC-2.1SL	Varian 2.1mm (14 G) ISOLIS™ Cryoprobe, 20cm Length, Spherical

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V. Intended Use/ Indications of Use Statement:

The ISOLIS cryoprobes, used with the CryoCare Systems, are intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The systems are designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. In addition, the systems are intended for use in the following indications:

General Surgery
- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of breast fibroadenomas
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions

Urology
- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Gynecology
- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology
- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Neurology
- Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology
- Ablation or freezing of skin cancers and other cutaneous disorders

Proctology
- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

Thoracic Surgery
- Ablation of cancerous lesions

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VI. Comparison of Technological Characteristics with the Predicate Device:

Technological differences between the subject and predicate devices are summarized below:

- **Probe Shaft Tip Angle**
  The trocar tip angle in the subject device has been reduced for a slightly sharper tip which will aid in piercing hard tumors.

- **Handle Construction**
  The subject device has a vacuum sleeve handle in comparison to the molded plastic handle in the predicate device to reduce overall size of the handle to provide stability and additional insulation.

- **Handle Materials**
  The subject device handle is made of heat shrink while the predicate device handle is made of plastic ABS injection molded handle covering a stainless-steel tube for a smaller, slimmer probe handle and provides better improved insulation.

- **Heat Exchanger**
  In comparison to the predicate device, the subject device's heat exchanger increases the surface area for thermal exchange and maximizes the freeze performance of the probes.

- **Accessories – Addition of Return Hose Clips**
  The subject devices have two Return Hose Clips added to the Return Hose to aid in the stability of the Return Hose and Probe and to maintain the position of the probe in the treatment location particularly during CT imaging that requires the patient to move in and out of a gantry.

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VII. Summary of the technological characteristics between subject and predicate devices

Feature and/or Specification	PREDICATE DEVICE(S) CRYOCARE TOUCH™ System and Accessories (K201588)	SUBJECT DEVICE(S) ISOLIS™ Cryoprobe	Comparison between predicate and subject devices and Rationale
Product Name	Slimline Cryoprobes	ISOLIS™ Cryoprobe	The subject devices are a line extension to the cryoprobes compatible with Varian Cryoablation Systems
Prescription/ Rx	Yes	Yes	Same
Compatible Varian Cryoablation Systems	CRYOCARE TOUCH System (K201588) CRYO-CS-3 Basic (K153489) Cryocare CS-3 V5 (K151968) Cryocare CS-3 V4 (K141110) Cryocare CS-3 (K101333) Cryocare SL (K011074) Cryocare-CS (K060279)	CRYOCARE TOUCH System (K201588) CRYO-CS-3 Basic (K153489) Cryocare CS-3 V5 (K151968) Cryocare CS-3 V4 (K141110) Cryocare CS-3 (K101333) Cryocare SL (K011074) Cryocare-CS (K060279)	Same
Intended Use / Indications of Use of the compatible Varian Cryoablation Systems	Intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery, and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. In addition, the CRYOCARE TOUCH System is intended for use in the following indications: **General Surgery** · Destruction of warts or lesions · Palliation of tumors of the oral cavity, rectum and skin · Ablation of breast fibroadenomas · Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area,	Intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery, and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. In addition, the systems are intended for use in the following indications: **General Surgery** · Destruction of warts or lesions · Palliation of tumors of the oral cavity, rectum and skin · Ablation of breast fibroadenomas · Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area,	Same

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	ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions **Urology** · Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia **Gynecology** · Ablation of malignant neoplasia or benign dysplasia of the female genitalia **Oncology** · Ablation of cancerous or malignant tissue · Ablation of benign tumors · Palliative intervention **Neurology** · Freezing of nerve tissue in pain management/ cryoanalgesia **Dermatology** · Ablation or freezing of skin cancers and other cutaneous disorders **Proctology** · Ablation of benign or malignant growths of the anus or rectum · Ablation of hemorrhoids **Thoracic Surgery** · Ablation of cancerous lesions	ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions **Urology** · Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia **Gynecology** · Ablation of malignant neoplasia or benign dysplasia of the female genitalia **Oncology** · Ablation of cancerous or malignant tissue · Ablation of benign tumors · Palliative intervention **Neurology** · Freezing of nerve tissue in pain management/ cryoanalgesia **Dermatology** · Ablation or freezing of skin cancers and other cutaneous disorders **Proctology** · Ablation of benign or malignant growths of the anus or rectum · Ablation of hemorrhoids **Thoracic Surgery** · Ablation of cancerous lesions	
Software	Not Applicable; Probes do not have software.	Not Applicable; Probes do not have software.	Not Applicable
Fundamental Technology	Joule-Thomson Effect	Joule-Thomson Effect	Same
Mechanism of Action (Freezing/Thawing Technology)	Operate on the Joule-Thomson Effect.	Operate on the Joule-Thomson Effect.	Same
Stick Function for ablation	Yes, via compatible Cryocare system	Yes, via compatible Cryocare system	Same
Activation Method	Software (Freeze, thaw, stop) via compatible Cryocare system	Software (Freeze, thaw, stop) via compatible Cryocare system	Same
Size of Isotherm	Size of isotherm is model specific as indicated in IFU Maximum diameter at -20°C = 25mm	Size of isotherm is model specific as indicated in IFU Maximum diameter at -20°C = 38mm	Improved isotherm performance

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Freeze Gas	Argon	Argon	Same
Thaw Gas	Helium	Helium	Same
Packaged Single-Use, Sterile and Disposable	Yes	Yes	Same
Sterilization	Gamma Irradiation	Gamma Irradiation	Same
Biocompatibility Classification	10993-1 Externally communicating medical device with tissue/bone/ dentin contact with limited duration (≤24 hours).	10993-1 Externally communicating medical device with tissue/bone/ dentin contact with limited duration (≤24 hours).	Same
Probe Construction			
Probe Shaft	304 Stainless Steel, 304L Stainless Steel (Tip)	304 Stainless Steel, 304L Stainless Steel (Tip)	Same
Probe Shaft Tip	Trocar Tip with 16° tip angle	Trocar Tip with 15° tip angle	Smaller trocar tip angle provides a sharper tip
Probe Shaft Insulation	Stainless steel 316LVM vacuum sleeve	Stainless steel 316LVM vacuum sleeve	Same
Probe Handle Construction and Materials	Plastic ABS injection molded handle covering a stainless-steel tube	Heat shrink (polyolefin or PVDF) covering a stainless-steel vacuum handle	Smaller and slimmer probe handle and provides better insulation
Heat Exchanger	Uses a copper screw-type cryostat for allowing thermal heat exchange of return gas to incoming gas.	Uses a copper-nickel alloy finned tubing coiled around a stainless-steel mandrel allowing thermal heat exchange of return gas to incoming gas.	The heat exchanger of the subject device increases the surface area for thermal exchange and maximizes the freeze performance of the probes.
Optional Feature	None	Two Return Hose Clips added to the Return Hose	Return Hose Clips added to the subject devices as an optional feature to aid in the stability of the Return Hose and the probes

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VIII. Performance Data (Non-Clinical Testing)

ISOLIS™ Cryoprobe underwent bench testing of the design and performance to demonstrate that the **ISOLIS Cryoprobe** meets the established design criteria and support the substantial equivalence with the predicate devices. The subject devices successfully completed functional, electrical safety, performance (non-functional), physical, usability, packaging, bioburden, gamma sterilization adoption, and biocompatibility evaluation and verified that the differences between the subject and predicate devices did not alter the overall risk profile.

IX. Performance Data (Clinical Testing and Animal)

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

X. Software

ISOLIS™ Cryoprobe does not have software and hence, no software update was required. Additionally, the use of ISOLIS™ Cryoprobe with Varian CryoCare Systems did not require any updates to system design (hardware and software).

XI. Substantial Equivalence Data

A comparison of the isotherm performance data between the subject and predicate devices at 0°C, -20°C, and -40°C shows that the isotherm sizes of the subject devices are within the established range of the isotherm sizes of the predicate devices.

In addition, the temperature-time history data of the subject and predicate devices at 0°C, -20°C and -40°C also show that the temperature profile of the subject devices is within the established range of the predicate devices with no substantial change to the coldest temperature achieved or rate of change in temperature.

In conclusion, the isotherm data demonstrates the isotherm performance and temperature-time history of the subject and predicate devices are similar and therefore, the isotherm performance of the subject devices and predicate devices is substantially equivalent.

XII. Conclusion

ISOLIS Cryoprobe is a new family of probes and introduces few design changes to the features when compared to the predicate device. These changes were made to provide improved performance and user experience while maintaining the overall risk profile.

The outcomes observed in the performance testing, Verification and Validation demonstrate that the device is as safe and effective as the predicate. Further, the indications for use and principle of operation are identical to the predicate device. Varian, therefore, believes the data demonstrates that the subject device ISOLIS Cryoprobe is substantially equivalent to the predicate device, Slimline probes.