August 11, 2020

Varian Medical Systems, Inc.
Mr. Peter Coronado
Senior Director Regulatory Affairs
3100 Hansen Way, m/s E110
Palo Alto, California 94304

Re: K201588
Trade/Device Name: CRYOCARE TOUCH System and Accessories

Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 11, 2020
Received: June 12, 2020

Dear Mr. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201588

Device Name
CRYOCARE TOUCH™ System and Accessories

Indications for Use *(Describe)*
The CRYOCARE TOUCH™ System is 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 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, 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.

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."

Endocare, Inc.
9825 Spectrum Drive
Building 2, Suite 250
Austin, TX 78717
www.varian.com

PREMARKET NOTIFICATION

K201588 510(k) Summary

CRYOCARE TOUCH™ System and Accessories

The following information is provided as required by 21 CFR 807.92

I. Submitter's Name:

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto, CA 94304

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: 11 June 2020

II. Device Information:

Proprietary Name:	CRYOCARE TOUCH™ System and Accessories
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 CS™ Surgical System (K153489)

IV. Device Description:

The CRYOCARE TOUCH™ System and accessories are a cryotherapy delivery system that is used to freeze/ablate tissue by the application of extreme cold temperatures.

The **CRYOCARE TOUCH** System is a standalone surgical system. The system consists of a compact, easy-to-operate console and associated accessories that include Endocare™ Cryoprobe devices to deliver cold temperatures to the therapeutic tissue and Endocare TempProbe™ Devices to monitor temperatures in the surrounding tissue. The system utilizes the Joule-Thomson effect and inert argon and helium gases to provide cryotherapy and is comprised of the following:

- **CRYOCARE TOUCH** Control Console
- 15-inch LCD Touchscreen Monitor with folding Monitor Arm
- Side Handles to facilitate mobility
- Wheels with wheel locks
- Power Supply
- Argon Port, Regulator, and Supply Line
- Helium Port, Regulator, and Supply Line
- Cryoprobe Interface with eight (8) cryoprobe connections
- TempProbe Interface with eight (8) **TempProbe** connections
- Alarm Audio Output on Back Panel
- Remote Keypad

The **CRYOCARE TOUCH** system software manages the therapy delivered to the patient by the **Endocare** cryoprobes. The cryoprobes are designed to deliver cold temperatures for cryotherapy using high-pressure argon gas circulated through the cryoprobe. Active tissue thawing is achieved by circulating helium gas through the cryoprobe. The refrigerative and warming capacity is limited to the distal end of the probe shaft.

Endocare Cryoprobes consists of the following cryoprobe families:

- Variable Ice ("V-Probe™") Cryoprobes in straight and right-angle configurations with model numbers CVA2400, CVA2400RA.
- Endocare™ Right Angle Cryoprobes with model numbers R3.8 and R3.8L.
- Endocare™ Cryoprobes in straight configuration with model number CRYO-48-F.
- Slimline™ Cryoprobes in right-angle configuration with model numbers PCS-17, PCS-17R, PCS-17RS, RS-17, RS-17L, PCS-24, PCS-24L, RS-24, RS-24L.

The TempProbe™ device is designed for use with the **Endocare Cryocare** Systems to monitor tissue temperatures in or around the targeted freeze zone. The **TempProbe** devices has model number CRYO-54-F and CRYO-55-F.

The **Endocare** Cryoprobes and **TempProbe** devices are previously cleared within K153489, except for the PCS-17RS cryoprobe model number which is included as a line extension within K201588. Additionally, K201588 proposes a standalone indicate for use the Endocare Cryoprobes (excluding the TempProbe devices). The proposed indication is included in the following section.

V. Indications for Use:

The CRYOCARE TOUCH™ System is 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 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, 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

VI. Comparison of Technological Characteristics with the Predicate Device:

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

- Removal of indication for ablation of arrhythmic cardiac tissue
- Touchscreen user interface
- Addition of pressure transducers
- Corresponding software updates to incorporate the touchscreen and pressure transducers
- Line extension to include model number PCS-17RS as a compatible accessory

The tables below include a high-level comparison of the predicate and subject devices.

Table 1. – Predicate and Subject Device Comparison – CRYOCARE TOUCH System and Accessories

Feature and/ or Specification	Subject Device CRYOCARE TOUCH System and Accessories	Predicate Device Cryocare CS Surgical System and Accessories	Comparison between Subject and Predicate
510(k)	K201588	K153489	N/A
Indications for use	The Cryocare CS Surgical System is 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 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, 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	The CRYOCARE TOUCH™ System is 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 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, 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	Subject Device removes the indication for "Ablation of arrhythmic cardiac tissue"

Table 1. – Predicate and Subject Device Comparison – CRYOCARE TOUCH System and Accessories

Feature and/ or Specification	Subject Device CRYOCARE TOUCH System and Accessories	Predicate Device Cryocare CS Surgical System and Accessories	Comparison between Subject and Predicate
	• 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 arrhythmic cardiac tissue • Ablation of cancerous lesions	• 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	
Mechanism of Action	Joule-Thomson Effect	Joule-Thomson Effect	Same
Freeze Gas	Argon	Argon	Same
Thaw Gas	Helium	Helium	Same
Human Interface Device/ Connections	1x Touchscreen 1 X Remote Keypad	1x Integrated Main Keyboard 1 X Remote Keypad	Subject devices incorporate touchscreen capability

Table 2. Predicate and Subject Device Comparison - PCS-17RS Cryoprobe

Feature and/ or Specification	Subject Device: PCS-17RS Endocare™ 1.7mm Round Ice PerCryo™ Cryoprobe, Short	Predicate Device: PCS-17R Endocare™ 1.7mm Round Ice PerCryo™ Cryoprobe	Comparison between Subject and Predicate
510(k)	K201588	K153489	N/A
Model	PCS-17RS	PCS-17R	New Model Number
Indications for use	Shares the **CRYOCARE TOUCH** System indications for use.	Shares the **CRYOCARE CS** Surgical System indications for use.	Same
Shaft Diameter	1.7 mm	1.7 mm	Same
Shaft Length	7 cm	15 cm	Subject device has shorter shaft length
Shape of Probe Tip	Trocar	Trocar	Same
Usage	Sterile, Single-Use	Sterile, Single-Use	Same

VII. Performance Data (Non-Clinical Testing)

Design Verification and Design Validation testing were completed to demonstrate that the **CRYOCARE TOUCH** System and Accessories performs as intended and meets its essential performance specifications:

- Each individual port displays the type of the probe connected adjacent to the port controls.
- Monitor/ Screen must display temperature values of each probe (Cryoprobe and TempProbe) used for the cryoablation treatment. Temperature values shall be within +/- 3 °C of the displayed value from -150°C to 40°C.
- Monitor/ Screen must display the freeze, stick and thaw duration time; the time shall have an accuracy of +/- 1 second.
- System must display a warning and alarm if unexpected behavior is observed.

The system software for the subject device is considered to have a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

The biocompatibility testing of the Endocare cryoprobes was intended to demonstrate the biological safety of the subject cryoprobe model number PCS-17RS.

The sterilization validation testing of the Endocare cryoprobes was intended to demonstrate that the gamma radiation sterilization method achieves cryoprobe sterility.

Bench testing included testing of the system, software, and cryoprobes, including:

- Electrical Safety Testing in accordance with IEC 60601-1.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2.
- Human Factors and Usability Testing in accordance with IEC 60601-1-6 and IEC 62366.
- Alarm system testing in accordance with IEC 60601-1-8.
- Software development in accordance with IEC 62304 and the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- PCS-17RS Cryoprobe Biocompatibility Testing in accordance with ISO 10993 series of standards, including ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12.
- PCS-17RS Cryoprobe Sterilization Validation in accordance with ISO 11137-1, ISO 11137-2, 11137-3, ISO 11737-1, and ISO 11737-2.

Test results showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

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 modernize the user interface.

The Intended Use and 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 the **CRYOCARE TOUCH** System and Accessories is substantially equivalent to the predicate device, **CRYOCARE CS** Surgical System and Accessories.

IX. Conclusion

The assessment following the outcomes observed in the performance testing and software design verification and design validation determines that the **CRYOCARE TOUCH** System and Accessories conforms to the defined user needs and intended uses. Varian therefore considers the **CRYOCARE TOUCH** System and Accessories to be safe and effective and to perform at least as well as the predicate device.