December 9, 2025

Focused Cryo, Inc.
Ryan Kruchten
VP of Engineering
1205 Johnson Ferry Road
Suite 136 - 336
Marietta, Georgia 30068

RE: K250742
Trade/Device Name: Focused Cryotherapy System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: November 7, 2025
Received: November 7, 2025

Dear Ryan Kruchten:

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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2025.12.09 00:08:28 -05'00'

For
Colin Kejing Chen, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250742

Device Name

Focused Cryotherapy System

Indications for Use *(Describe)*

The Focused Cryotherapy System is intended for cryoablative destruction of tissue during surgical procedures. The Focused Cryotherapy System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, nerves, tumors, and skin lesions.

In addition, the system is intended for use in the following indications:

Urology

• Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)

Oncology

• Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention. Palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard radiation therapy

Dermatology

• Ablation or freezing of skin cancers and other cutaneous disorders
• Destruction of warts or lesions, 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, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin

Gynecology

• Ablation of malignant neoplasia or benign dysplasia of the female genitalia

General surgery

• Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas

ENT

• Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth

Thoracic Surgery

• (with the exception of cardiac tissue)

Proctology

• Ablation of benign or malignant growths of the anus or rectum

Neurology

• Freezing of nerve tissue in pain management/cryoanalgesia

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.

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Focused Cryo, Inc.
101 Nerem St NW
Suite 1000
Atlanta, GA 30313

PREMARKET NOTIFICATION
K250742 510(k) Summary
Focused Cryotherapy System
The following information is provided as required per 21 CFR 807.92

1. **Submitter's Name:**
Focused Cryo, Inc.
101 Nerem St. NW
Suite 1000
Atlanta, GA 30313

Contact Name: Mr. Ryan Kruchten, VP of Engineering
Phone: 952-484-3166
E-mail: rkruchten@focusedcryo.com
Date Prepared: December 4, 2025

2. **Device Information:**

Proprietary Name:	Focused Cryotherapy System
Common/Usual Name:	Cryosurgical unit and accessories
Classification Name:	Cryosurgical unit and accessories
Regulation Number:	21 CFR 878.4350
Product Code:	GEH

3. **Predicate Devices:**
Primary: CRYOCARE TOUCH™ System and Accessories (K201588)
Secondary: Visual-ICE Cryoablation System (K230551)

4. **Device Description:**
The Focused Cryotherapy System is a cryoablation platform that contains the following components:
   - Probe (FC-2021CD01)
   - Console (FC-AR401)
   - Software

The Focused Cryotherapy System is a cryoablation platform for use in the cryoablation of nerves and tumors. The Probe is a handheld, single use, cryosurgical instrument. The

Probe utilizes a high-pressure cryogen (argon gas) to freeze target tissues, creating an inflammatory response, and ultimately, cryonecrosis. In use with tumors, temperatures below -40°C is the temperature at which intracellular ice formation occurs which is lethal for cells. When applied to nerves, temperatures below -20°C cause extracellular ice formation along axonal tubes which causes cessation of action potential conduction. When high pressure argon gas is supplied to the Probe via the Console, rapid cooling is achieved via the Joule-Thomson effect. The Probe incorporates a heating element to facilitate directional cryoablation. The Console has combination gas/electrical ports to handle 4 Probes in parallel. The Console contains the Firmware and Software. The System consists of a main chassis (Console) for the cooling system, Firmware, Software, controls, touch screen and Probe ports. Safety measures of the system include audible and visual alarms, safety valves, and emergency shutoff button.

5. **Indications for Use:**

The Focused Cryotherapy System is intended for cryoablative destruction of tissue during surgical procedures. The Focused Cryotherapy System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, nerves, tumors, and skin lesions.

In addition, the system is intended for use in the following indications:

Urology

- Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)

Oncology

- Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention. Palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard radiation therapy

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders
- Destruction of warts or lesions, 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, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin

Gynecology

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

General surgery

- Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas

ENT

- Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth

Thoracic Surgery

- (with the exception of cardiac tissue)

Proctology

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

Neurology

- Freezing of nerve tissue in pain management/cryoanalgesia

6. 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:

- Electrical heating element
- Directionally-biased ablation zones
- Cryogen pressure utilized
- Length of the cryoprobe active region

The table below includes a high level comparison of the Subject and Predicate Devices:

Table 1 – Predicate and Subject Device Comparison – Focused Cryotherapy System

Characteristic	**Subject Device: Focused Cryotherapy System**	**Secondary Predicate Device: Visual-ICE Cryoablation System**	**Primary Predicate Device: Cryocare Touch System**	**Comparison Between Subject and Predicate Devices**
510(k) Number	K250742	K230551	K201588	N/A
Manufacturer	Focused Cryo, Inc.	Boston Scientific	Varian Medical Systems	N/A
Regulation	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350	Same
Product Code	GEH	GEH	GEH	Same
Classification	Class II	Class II	Class II	Same
Device Type	Cryosurgical Unit and Accessories	Cryosurgical Unit and Accessories	Cryosurgical Unit and Accessories	Same
Intended Use	Freeze/ablate tissue by the application of extreme cold temperatures	Freeze/ablate tissue by the application of extreme cold temperatures	Freeze/ablate tissue by the application of extreme cold temperatures	Same
Indications for Use	The Focused Cryotherapy System is intended for cryoablative destruction of tissue during surgical procedures. The Focused Cryotherapy System is indicated for use as a	The Visual-ICE™ Cryoablation System is intended for cryoablative destruction of tissue during surgical procedures. The Visual-ICE™ Cryoablation System is indicated for use as	The CRYOCARE TOUCH™ System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology,	The Subject Device has the same indications for use as the Secondary Predicate, except for the addition

	cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, nerves, tumors, and skin lesions. In addition, the system is intended for use in the following indications: **Urology** • Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH) **Oncology** • Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention. Palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard radiation therapy **Dermatology** • Ablation or freezing of skin cancers and other cutaneous disorders • Destruction of warts or lesions, 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, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin **Gynecology** • Ablation of malignant neoplasia or benign dysplasia of the female genitalia	a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, and skin lesions. The Visual-ICE Cryoablation System has the following specific indications: • **Urology** Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH) • **Oncology** Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention. Palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard radiation therapy • **Dermatology** Ablation or freezing of skin cancers and other cutaneous disorders Destruction of warts or lesions, 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, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin • **Gynecology** Ablation of malignant neoplasia or benign dysplasia of the female genitalia • **General surgery**	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**	of the neurology indication, which it shares with the Primary Predicate.

	General surgery • Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas **ENT** • Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth **Thoracic Surgery** • (with the exception of cardiac tissue) **Proctology** • Ablation of benign or malignant growths of the anus or rectum **Neurology** • Freezing of nerve tissue in pain management/cryoanalgesia	Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas • **ENT** Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth • **Thoracic Surgery** (with the exception of cardiac tissue) • **Proctology** Ablation of benign or malignant growths of the anus or rectum	• 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 / Principle of Operation	Joule-Thomson Effect	Joule-Thomson Effect	Joule-Thomson Effect	Same
Freeze Gas	Argon	Argon	Argon	Same
Operating Pressure (psi)	3500	3500	3200	Same as Secondary Predicate
Thaw Mechanism	Heating element based	Heating element based	Helium	Same as Secondary Predicate
Number of Simultaneously Active Probes / Channels	4 channels/active needle ports	8 channels/active needle ports	8 channels/active needle ports	The Subject Device supports fewer cryoprobes for simultaneous operation.
Console Freeze Modes	Circumferential, Directional	Circumferential	Circumferential	The Subject Device has a second operating mode that produces a directionally biased ablation zone.
User Interface	Touchscreen	Touchscreen	Touchscreen and remote keypad	Same as Secondary Predicate
Probe Temperature Sensor	Internal Thermocouple at Tip	Internal Thermocouple at Tip	Internal Thermocouple at Tip	Same
Temperature Feedback	Software Enabled	Software Enabled	Software Enabled	Same
Probe Diameter	2.1 mm	1.5 and 2.1 mm	1.7 and 2.4 mm	Same as one configuration of

				Secondary Predicate.
Probe Length	20 cm	10, 17.5, and 23 cm	7, 15, and 23 cm	Similar to Predicate devices. Probe Length is within the bounds of predicate probe lengths.
Probe Tip	Trocar	Trocar	Trocar	Same
Probe Material	Stainless Steel	Stainless Steel	Stainless Steel	Same
Probe Sterility	Sterile, Single-Use	Sterile, Single-Use	Sterile, Single-Use	Same

7. Performance Data (Non-Clinical Testing):

Verification and validation testing was conducted in accordance with applicable international standards and internal requirements to ensure safety, effectiveness, and compliance.

Verification testing included the following:

- **System Verification:** Confirmed proper functionality of Probes, Console, and Software
- **Mechanical Testing:** Evaluated gas components, Probe integrity, and packaging durability
- **Electrical Safety & EMC Testing:** Conducted per IEC 60601-1 and IEC 60601-1-2 standards
- **Software Verification & Validation:** Developed per IEC 62304 and FDA software guidance, verified all software requirements
- **Biocompatibility Testing:** Conducted per ISO 10993 series

Validation testing included the following:

- **Human Factors Testing:** Assessed usability per IEC 60601-1-6, IEC 62366 and FDA human factors guidance
- **Sterilization Validation:** Ensured compliance with ISO 11135 and related standards.
- **Ex-Vivo Tissue Testing:** Testing was performed in porcine tissue samples to validate device tissue effects and quantify thermal performance and temperature-time histories.
- **Isotherm Comparative Testing:** Head-to-head comparison testing was performed with the predicate device to demonstrate substantially equivalent isothermal contours.

All performance tests met predefined acceptance criteria, demonstrating that the Focused Cryotherapy System is as safe and effective as the predicate device. No new risks to safety or effectiveness were identified. No animal or clinical studies were included in this submission.

8. Determination of Substantial Equivalence to the Predicate Device:

A subset of technological characteristics and features of the subject device differs from the predicate device. However, these differences do not raise different questions of safety and effectiveness when compared to the predicate devices. Performance data demonstrate that the subject device is as safe and effective as the predicate devices for the same intended use, thereby supporting a determination of substantial equivalence. The subject device has the same intended use as the predicate devices.

9. Conclusion:

The assessment following the outcomes observed in the performance testing and design verification and design validation determines that the Focused Cryotherapy System conforms to the defined user needs and intended uses in both circumferential and directional ablation modes. Focused Cryo, therefore, considers the Focused Cryotherapy System to be safe and effective and to perform at least as well as the predicate devices.