January 29, 2025

Hygea Medical Technology Co., Ltd.
Xingtong Jiang
Deputy General Manager
Floor 6&7, West Area of Building No. 8, No.30 YuHua Road,
Shunyi
Beijing, Beijing 101318
China

Re: K243042
Trade/Device Name: Co-Ablation System with Sterile Co-Ablation Probe
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 27, 2024
Received: December 30, 2024

Dear Xingtong Jiang:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2025.01.29 13:46:22 -05'00'

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)*
K243042

Device Name
Co-Ablation System with Sterile Co-Ablation Probe

Indications for Use *(Describe)*
The Co-Ablation System with Sterile Co-Ablation Probe is designed to destroy solid tumors, 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 Co-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 also 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 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 and 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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510(k) Summary

Co-Ablation System with Sterile Co-Ablation Probe

1. Submission Sponsor

Hygea Medical Technology Co., Ltd.
Floor 6&7, West Area of Building No. 8, No.30 YuHua Road, Shunyi,
101318 Beijing
PEOPLE'S REPUBLIC OF CHINA

Contact Name: Mr.Xingtong Jiang, Deputy General Manager
Email: djq@hygeamed.com
Phone:+86-010-82158025

2. Date Prepared

Sep 25th 2024

3. Device Identification

Trade/Proprietary Name:	Co-Ablation System with Sterile Co-Ablation Probe
Regulation Number:	21 CFR 878.4350
Regulation Name:	Cryosurgical Unit And Accessories
Regulatory Class:	Class II
Regulatory Class:	GEH

4. Predicate Device(s):

CRYOCARE TOUCH™ System and Accessories (k201588)

Manufacturer: Varian Medical Systems, Inc.

XSense Cryoablation System with CryoProbes(K240892)

Manufacturer: IceCure Medical Ltd.

ISOLIS Cryoprobe(K230271)

Manufacturer: Varian Medical Systems, Inc.

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, it 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 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.

The XSense Cryoablation System with CryoProbes is operated in conjunction with an imaging system, such as ultrasound, to provide real-time visualization of the cryosurgical procedure, used in a professional healthcare environment for cryotherapy according to IceCure Medical's technology. The device technology is based on the delivery of the low temperature cryogen under pressure from the internal dewar to the CryoProbe's tip, enabling it to reach very low temperature, due to the thermal energy transfer principle that occurs as a result of phase transfer from liquid to gas of nitrogen at the tip of the CryoProbe, and thus freeze and destroy the treated tissue that the CryoProbe comes in contact with.

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.

5. Device Description

The Co-Ablation System with Sterile Co-Ablation Probe is a device designed to freeze/ablate tissue. It utilizes phase change effect to generate extremely low temperature and high temperature to destroy lesion tissues with a combined working mode, to achieve better clinical efficacy, safety and efficiency.
Main components: Co-Ablation System, Sterile Co-Ablation Probe.
Accessory: Sterile Temperature Probe.

The Co-Ablation System is a mobile medical equipment. The Co-Ablation System consists a host of Co-Ablation System including liquid nitrogen storage tank (referred to as cryotank), cryo-valve, warm working medium storage tank (referred to as warmtank), warm-valve, waste bottle,insulated pipe and control/display system, etc. The Co-Ablation System has model number with AI Epic S40U and AI Epic S20U.

The Sterile Co-Ablation Probe is a single-use sterile product, consisting of a handle, quick release connector, probe tip and probe shaft. It must be used in conjunction with the Co-Ablation System. During treatment, the Sterile Co-Ablation Probe is inserted into the lesion to be ablated. The freezing channel is opened, and the freeze working medium (liquid nitrogen) rapidly flows to the probe and evaporates to absorb heat, rapidly freezing and

destroying tissue near the probe tip. When the system is switched from the freeze mode to warm mode, high temperature steam passes to the tip of the Sterile Co-Ablation Probe, rapidly heating the tip portion of the Sterile Co-Ablation Probe so that the frozen tissue around the Sterile Co-Ablation Probe is quickly melted, and the Sterile Co-Ablation Probe is easily pulled out. The Sterile Co-Ablation Probe consists of right-angle and straight configurations with model number Elite, and comprises 20 specifications as listed below:

Model	Specifications	Structural Form
Elite	ACL17	Straight shaped
	ACS17	
	ACX17	
	ABL20	
	ABS20	
	ABX20	
	ADL26	
	RCL17	Right-angled shaped
	RCS17	
	RCX17	
	RBL20	
	RBS20	
	RBX20	
	RBL26	
	RBS26	
	RBX26	
	RAL26	
	RAS26	
	RAL30	
	RAS30	

The Sterile Temperature Probe is designed for use with the Co-Ablation System to monitor temperatures in the surrounding tissue. The Sterile Temperature Probe with model number Ease, and comprises 4 specifications: TSS08, TSL08, TMS15 and TML15.

6. Intended Use and Indications for Use

The Co-Ablation System with Sterile Co-Ablation Probe is designed to destroy solid tumors, 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 Co-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 also 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 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 and rectum.
- Ablation of hemorrhoids.

Thoracic Surgery

- Ablation of cancerous lesions.

7. Comparison of Technological Characteristics with the Predicate Device

The following table compares the Co-Ablation System with Sterile Co-Ablation Probe to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 1 – Predicate and Subject Device Comparison - Co-Ablation System

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
510(k) Number	K243042	K201588	K240892	/
Regulatory Class	Class Ⅱ	Class Ⅱ	Class Ⅱ	Same
Regulation Name	Cryosurgical unit and accessories	Cryosurgical unit and accessories	Cryosurgical unit and accessories	Same
Product Code	GEH	GEH	GEH	Same
Regulation No.	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350	Same
Manufacturer	Hygea Medical Technology Co., Ltd.	Varian Medical Systems	IceCure Medical Ltd	/
Trade/Device Name	Co-Ablation System with Sterile Co-Ablation Probe	Cryocare TOUCH™ System and Accessories	XSense Cryoablation System with CryoProbes	/
Intended use	The Co-Ablation System with Sterile Co-Ablation Probe is designed to destroy solid tumors, intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology,	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	XSense Cryoablation System with CryoProbes is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. XSense Cryoablation System with CryoProbes is indicated for use as a cryosurgical tool in the fields of general surgery,	Same

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
	dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to Co-Ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.	designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.	dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including fibroadenomas, prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. XSense Cryoablation System with CryoProbes may be used with an imaging device such as an ultrasound to provide realtime visualization of the cryosurgical procedure.	
Indications for Use	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 mouth, angiomas, sebaceous hyperplasia, basal cell tumors of	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	General Surgery • Ablation of breast fibroadenomas, leukoplakia of 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,	The subject device is the same as the predicate device A, and compare to predicate device B, “Ablation of arrhythmic cardiac tissue” is not included.

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
	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	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	hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions. Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions. Destruction of warts or lesions. Palliation of tumors of the oral cavity, rectum, and skin. Urology • Ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH) Gynecology • Ablation of malignant neoplasia or benign dysplasia of the female genitalia Oncology • Ablation of cancerous or malignant tissue and benign tumors and palliative intervention Dermatology	

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
	• 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 and rectum • Ablation of hemorrhoids Thoracic Surgery • Ablation of cancerous lesions	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	• Ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions ENT (Ear, Nose, and Throat) • Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth. Proctology • Ablation of benign or malignant growths of the anus and rectum and hemorrhoids Thoracic Surgery • Ablation of arrhythmic cardiac tissue and cancerous lesions	
Use Environment	Professional healthcare environment	Professional healthcare environment	Professional healthcare environment	Same
Intended User	This system is only restricted to use in specific surgeries by qualified medical professionals and nursing staffs properly trained. Those who have not received adequate training on the	The users of the system must be physicians trained in their respective fields, supported by technicians trained in the operation of the system. Physicians should be either Urologists or Interventional	The user of the XSense cryoablation system only if you meet all the following criteria: You are a board certified medical practitioner licensed in your country. You have taken a certified IceSense3	Same

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
	use of this system are prohibited from operating or maintaining the system.	Radiologists. Technicians must be at least high school graduates who are subsequently trained in the operations of the Endocare Cryocare CS system. The technician works under the direction of the physician to operate the machine, including tank-set up, machine start-up, and operating the user interface.	cryoablation system training course. You have read and understood all relevant material accompanying theIceSense3 cryoablation system.	
Principles of Operation	Phase Change Effect	Joule-Thomson Effect	Phase Change Effect	The Subject Device is the same as the Predicate Device B, but they differ from the Predicate Device A.
Operation Mode	Freeze, Warm, Pause	Freeze, Thaw, Stick, Stop	Freeze, Thaw, Stick, Pause, Extraction	The subject Devices don't have stick mode.
Software Control	Procedure planning/Manual Operation.	Auto/Manual Freeze.	Automatic/Manual/Pre-programmed freezing cycles	Same Three devices have the same model, just only the description is minor difference.

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
Freeze Temperature at the Probe Tip	-186℃ ± 10℃	-150 ℃± 10 ℃	-196 ℃	The Subject Device and Predicate Device B have the same minimum temperature, which is lower than the Predicate Device A.
Cryogen	Liquid Nitrogen	Argon	Liquid Nitrogen	The Subject Device and Predicate Device B have the same Cryogen, Liquid Nitrogen. The Predicate Device A uses Argon as the cryogen.
Warm Temperature at the Probe Tip	75 ℃± 10 ℃	40 ℃	40 ℃	The temperature of the Subject Device is higher than that of both Predicate Devices

Feature		Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
Warming working fluid		Ethyl alcohol	Helium	Nitrogen gas	The three devices use different materials as the warming working fluid based on their own operating principle.
Safety		Under CT guidance, the tumor tissue boundary is clear, Co-Ablation System can control the ice ball size according to the image in real time to achieve the precise ablation.	Under CT guidance, the tumor tissue boundary is clear, Cryocare Touch™ System can control the ice ball size according to the image in real time to achieve the precise ablation.	Under CT guidance, the tumor tissue boundary is clear, XSense Cryoablation System can control the ice ball size according to the image in real time to achieve the precise ablation.	Same
Human Machine Interface		Touchscreen/Keyboard	Touchscreen/Remote Keyboard	Touchscreen/Cryohandle	Same
Probe Channel		S40U: Configure 1 to 4 S20U: Configure 1 to 2	1 to 8	1	The maximum number of channels is different.
Temperature Probe	**Channel**	1 to 4	1 to 8	1	The maximum number of channels is different.
	Disposable /Single use	Single use	Single use	Single use	Same

Feature		Subject Device Sterile Co-Ablation Probe	Predicate Device A Cryosurgical unit and accessories	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
	Sterility	EO	EO	EO	Same
	Biocompatibility Classification	Patient contact materials comply with ISO 10993-1	Patient contact materials comply with ISO 10993-1	Patient contact materials comply with ISO 10993-1	Same
	Patient Contacting Materials	304 Stainless steels	304 Stainless steels	304 Stainless steels	Same

Table 2 – Predicate and Subject Device Comparison - Sterile Co-Ablation Probe

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A ISOLIS Cryoprobe	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
510(k) Number	K243042	K230271	K240892	/
Manufacturer	Hygea Medical Technology Co., Ltd.	Varian Medical Systems	IceCure Medical Ltd	/
Probe Shaft	304 Stainless steels	304 Stainless steels	304 Stainless steels	Same
Probe Shaft Insulation	Vacuum	Vacuum	Vacuum	Same
Probe Shaft Tip	Trocar	Trocar	Trocar	Same
Outer Diameter (mm)	1.7/1.98/2.6/3.0	1.7/2.4/3.8	2.4/3.4	The three devices have different diameters.
Disposable /Single use	Single use	Single use	Single use	Same

Feature	Subject Device Sterile Co-Ablation Probe	Predicate Device A ISOLIS Cryoprobe	Predicate Device B XSense Cryoablation System with CryoProbes	Discussion
Sterility	EO	Gamma Irradiation	EO	The Subject Device and Predicate Device B are sterilized using the same sterilization method as EO. The Predicate Device B uses Gamma Irradiation.
Biocompatibility classification	Patient contact materials comply with ISO 10993-1	Patient contact materials comply with ISO 10993-1	Patient contact materials comply with ISO 10993-1	Same
Patient Contacting Materials	304 Stainless steels. Contact duration<24 hours	304 Stainless steels. Contact duration<24 hours	304 Stainless steels. Contact duration<24 hours	Same
Probe Pretest	Yes	Yes	Yes	Same

The intended uses and indications for use of Subject Device are substantially the same as the predicate devices, and the Subject Device has the similar technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Subject Device and the Primary Predicate Device raise no new issues of safety or effectiveness. Performance data demonstrate that the Subject Device is as safe and effective as the cleared the cleared XSense Cryoablation System (K240892), the cleared Cryocare TOUCH™ System(K201588) and the cleared ISOLIS Cryoprobe (K230271).

8. Performance Data (Non-Clinical Testing)

Hygea completed the following non-clinical tests. The Co-Ablation System with Sterile Co-Ablation Probe passed the testing in accordance with internal requirements, national standards, and international standards shown below. The test results support the device substantial equivalence to the predicate device:

Electrical Safety:

- The Co-Ablation System with Sterile Co-Ablation Probe meets the basic safety and essential performance for the intended use and use environment in accordance with ANSI/AAMI ES60601-1.

Electromagnetic Compatibility (EMC)

- The Co-Ablation System with Sterile Co-Ablation Probe meets the EMC requirement for the intended use and use environment in accordance with IEC 60601-1-2.

Usability Testing

- The usability testing of Co-Ablation System with Sterile Co-Ablation Probe is to evaluate the user interface in accordance with IEC 60601-1-6 and IEC 62366.

Software Testing

- The software development is in accordance with IEC 62304, FDA guidance for the content of premarket submissions for software contained in Medical devices and FDA guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. And the software verification/validation met the acceptance criteria.

Sterilization Testing

- The Sterile Co-Ablation Probe and Sterile Temperature Probe are sterilized by EO, the validation was performed in accordance with ISO 11135, ISO 11737-1,ISO 11737-2,ISO11607-1, ISO 11607-2.

Biocompatibility Testing

- The applied parts of Sterile Co-Ablation Probe and Sterile Temperature Probe are inserted into the tissue and limited contact is less than 24 hours, the biocompatibility testing was performed in accordance with ISO 10993 related standards.

Shelf Life Testing

- The aging testing and packaging testing were performed to verify the validity of shelf life and packaging of Co-Ablation System with Sterile Co-Ablation Probe.

Ex-vivo Testing

- The Co-Ablation System with Sterile Co-Ablation Probe were performed the ex-vivo testing, co-ablation volume correlates with treatment area length, tip diameter, and freezing time. The longer the treatment area, the larger the probe diameter, and the longer the duration of cryogenics, the larger the volume of ice ball formed and the larger the area of tumor that can be clinically covered, without increasing inadvertent damage to surrounding tissue.

Additional Performance Testing:

- The Co-Ablation System with Sterile Co-Ablation Probe ice ball verification testing.
- Sterile Temperature Probe measurement accuracy verification testing.

Animal Testing:

- The Co-Ablation System with Sterile Co-Ablation Probe were performed the animal testing, which indicated that Sterile Co-Ablation Probe of different diameters corresponding to different cold zones could produce ice balls of different sizes under the same ablation scheme, providing a basis for clinicians to treat tumors of specific sizes, different specifications can better meet clinical needs. And throughout all ablation treatments, the ECG monitoring results showed stable vital signs in the animals, all the subject devices could be used with the desired functions, no abnormalities of the device was observed, and the operability was good. It was validated fully the efficacy, safety and usability of the product, without the additional safety and performance risk.

9. Performance Data (Clinical Testing)

No clinical data was necessary to determine the substantial equivalence of this device.

10. Conclusion

The intended uses and indications for use are substantially the same as the predicate devices, and the Co-Ablation System with Sterile Co-Ablation Probe has the similar technological characteristics, and principles of operation as the predicate devices. The minor technological differences do not raise new or different questions of safety and effectiveness, the non-clinical performance testing has demonstrated the Co-Ablation System with Sterile Co-Ablation Probe is as safe and effective as the predicate devices. Therefore, the Co-Ablation System with Sterile Co-Ablation Probe are substantially equivalent to the predicate devices.