



February 24, 2025

IceCure Medical , Ltd.
Maayan Levi
Regulatory Affairs Director
7 Haeshel St.
P.O.b 3163
Caesarea, 3079504
Israel

Re: K260377

Trade/Device Name: XSense Cryoablation System with CryoProbes
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 5, 2026
Received: February 5, 2026

Dear Maayan Levi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

**Colin K.
Chen -S**

Digitally signed by
Colin K. Chen -S
Date: 2026.02.24
10:22:24 -05'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260377

Please provide the device trade name(s).

XSense Cryoablation System with CryoProbes

Please provide your Indications for Use below.

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, 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 real-time visualization of the cryosurgical procedure.

The system has the following specific indications:

- Urology - ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH).
- Oncology - ablation of cancerous or malignant tissue and benign tumors and palliative intervention.
- Dermatology - ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions.
- Gynecology - ablation of malignant neoplasia or benign dysplasia of the female genitalia.
- ENT (Ear, Nose and Throat) - Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth.
- 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, 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.
- Thoracic Surgery - ablation of arrhythmic cardiac tissue and cancerous lesions.
- Proctology - ablation of benign or malignant growths of the anus and rectum and hemorrhoids.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

XSense Cryoablation System with CryoProbes

Applicant Name: IceCure Medical Ltd.
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Caesarea, 3079504, Israel
Telephone: +972-4-6230333

Contact Person: Maayan Levi,
Regulatory Affairs Director
IceCure Medical Ltd.
MaayanL@icecure-medical.com

Date Prepared: February 05, 2026

Trade Name: XSense Cryoablation System with CryoProbes

Classification Name: 21 CFR 878.4350

Product Codes: GEH

Classification: Class II Medical Device

Review Panel: General and Plastic Surgery

Predicate Device: XSense Cryoablation System with CryoProbes (K240892)

Intended Use/Indication for Use:

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, 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 real-time visualization of the cryosurgical procedure.

The system has the following specific indications:

Field	Indication
Urology	Ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH).
Oncology	Ablation of cancerous or malignant tissue and benign tumors and palliative intervention.
Dermatology	Ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions.
Gynecology	Ablation of malignant neoplasia or benign dysplasia of the female genitalia.
ENT (Ear, Nose, and Throat)	Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth.
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, 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.
Thoracic Surgery	Ablation of arrhythmic cardiac tissue and cancerous lesions.
Proctology	Ablation of benign or malignant growths of the anus and rectum and hemorrhoids.

1.1 Device Description:

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 XSense Cryoablation System with CryoProbes cleared under (K240892) is the predicate device of the subject device XSense Cryoablation System with CryoProbes, which is part of the IceCure family of cryoablation products. No change other than the Shelf-life of two (2) years was introduced since last cleared under (K240892). The XSense Cryoablation System include the following additional accessories: (1) CryoProbes that are available in two configurations, (2) an external 25 liters dewar with a supporting cart, (3) an Introducer, and (4) a Holder.

1.2 Performance Data:

The subject device, XSense Cryoablation System with CryoProbes, and the predicate device, XSense Cryoablation System with CryoProbes (K240892), are the same device with an update to the CryoProbes' Shelf-life. Except for Shelf-life validation, all other Verification and Validation (V&V) activities for the subject device, were not impacted, modified or updated since the predicate device's submission (K240892).

The validation of the change of XSense CryoProbe's Shelf-life from one (1) year to two (2) years passed successfully all predefined acceptance criteria according to well-established-FDA-recognized consensus standards (with no deviations from the standards), this demonstrated that the difference in the technological characteristics between the subject and predicate devices do not raise any new types of safety or efficacy concerns.

1.3 Substantial Equivalence:

The XSense Cryoablation System with CryoProbes and its predicate device (K240892) have the same intended use, indications for use, principles of operation, and similar technological characteristic. They are the same device with no change other than Shelf-life to the technological characteristics. This 510(K) introduces an isolated change to Shelf-life which was validated according to well-established-FDA-recognized consensus standard.

The comparison table below describes the similarities and the isolated difference between the subject device, XSense Cryoablation System with CryoProbes, and its predicate device, (K240892), providing detailed information regarding the basis for the determination of substantial equivalence.

	Subject Device	Predicate Device	Comparison
Device Name	XSense Cryoablation System with CryoProbes (K)	XSense Cryoablation System with CryoProbes (K240892)	
510(k) Number	K	K240982	--
Product Code	GEH	GEH	Same
Device	Cryotherapy system	Cryotherapy system	Same
Intended Use	The system is intended for cryogenic destruction of tissue during surgical procedures.	The system is intended for cryogenic destruction of tissue during surgical procedures.	Same
Indications for Use	XSense cryoablation system is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. XSense cryoablation system is indicated for use as a cryosurgical tool in the fields of general surgery, 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 may be used	XSense cryoablation system is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. XSense cryoablation system is indicated for use as a cryosurgical tool in the fields of general surgery, 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 may be used	Same

	Subject Device	Predicate Device	Comparison
Device Name	XSense Cryoablation System with CryoProbes (K)	XSense Cryoablation System with CryoProbes (K240892)	
	<p>with an imaging device such as an ultrasound to provide real-time visualization of the cryosurgical procedure.</p> <p>The system has the following specific indications:</p> <ul style="list-style-type: none"> • <u>Urology</u> - ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH). • <u>Oncology</u> - ablation of cancerous or malignant tissue and benign tumors and palliative intervention. • <u>Dermatology</u> - ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions. • <u>Gynecology</u> - ablation of malignant neoplasia or benign dysplasia of the female genitalia. • <u>ENT</u> - Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth. • <u>General Surgery</u> - 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, 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 	<p>with an imaging device such as an ultrasound to provide real-time visualization of the cryosurgical procedure.</p> <p>The system has the following specific indications:</p> <ul style="list-style-type: none"> • <u>Urology</u> - ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH). • <u>Oncology</u> - ablation of cancerous or malignant tissue and benign tumors and palliative intervention. • <u>Dermatology</u> - ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions. • <u>Gynecology</u> - ablation of malignant neoplasia or benign dysplasia of the female genitalia. • <u>ENT</u> - Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth. • <u>General Surgery</u> - 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, 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 	

	Subject Device	Predicate Device	Comparison
Device Name	XSense Cryoablation System with CryoProbes (K)	XSense Cryoablation System with CryoProbes (K240892)	
	tumors of the oral cavity, rectum, and skin. • <u>Thoracic Surgery</u> - ablation of arrhythmic cardiac tissue and cancerous lesions. • <u>Proctology</u> - ablation of benign or malignant growths of the anus and rectum and hemorrhoids.	tumors of the oral cavity, rectum, and skin. • <u>Thoracic Surgery</u> - ablation of arrhythmic cardiac tissue and cancerous lesions. • <u>Proctology</u> - ablation of benign or malignant growths of the anus and rectum and hemorrhoids.	
CryoProbe's Shelf-Life	2 years	1 year	Different- This change will be reflected in a labeling change in the CryoProbes' instructions for use and direct labels (expiration date). In addition to the extended Shelf-life the change was evaluated and validated based on a more suitable method according to a well-established-FDA-recognized consensus standards, all results met predefined acceptance criteria (with no deviations from the standards), and therefore this difference does not present new questions of safety or efficacy.

As described in the comparison table above the XSense Cryoablation System with CryoProbes and the predicate device (K240892) have the same intended use, indications for use, principles of operation, and similar technological characteristics. The difference between the XSense Cryoablation System with CryoProbes device and its predicate does not raise any new issues of safety or effectiveness. This supported by Shelf-life validation conducted on the subject device.

1.4 Conclusions:

The XSense Cryoablation System with CryoProbes is substantially equivalent to its predicate device, the XSense Cryoablation System with CryoProbes cleared under (K240892) which is part of the IceCure family of cryoablation products.