June 28, 2024

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

Re: K240892
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: March 31, 2024
Received: April 1, 2024

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 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.

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: 2024.06.28 16:44:31 -04'00'

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)*
K240892

Device Name
XSense Cryoablation System with CryoProbes

Indications for Use *(Describe)*
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.

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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XSense Cryoablation System with CryoProbes 510(K) Summary

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: March 31, 2024

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: ProSense™ Cryoablation System which was cleared as part of IceCure Family Cryoablation System (IceSense™3, ProSense™, and MultiSense™) (K183213)

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 and Technological Characteristics:

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 is the next generation of its predicate- the already cleared ProSense™ Cryoablation System (K183213) and is part of the IceCure family of cryoablation products. The XSense Cryoablation System with CryoProbes operates in the same manner as the previous design of the ProSense™ Cryoablation System. The XSense Cryoablation System will 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:

IceCure Medical Ltd. conducted several performance tests to demonstrate that the XSense Cryoablation System with CryoProbes complies with performance standards and that it functions in a safe and effective manner, as intended.

The XSense Cryoablation System with CryoProbes underwent performance testing such as software verification and validation testing, biocompatibility, sterilization (EtO), shelf life, electrical safety, and electromagnetic compatibility (IEC 60601-1, IEC 60601-1-2 and IEC TR 60601-4-2) testing. These performance tests in addition to the bench tests and usability study, demonstrated that the differences in the technological characteristics between the subject and predicate devices do not raise any new types of safety or efficacy concerns. All tests were performed according to recognized standards and relevant FDA guidance.

1.3 Substantial Equivalence:

The following table compares the subject XSense Cryoablation System with CryoProbes to the predicate device (ProSense™ Cryoablation System which was cleared as part of IceCure Family of Cryoablation System (IceSense™3, ProSense™, and MultiSense™) (K183213)) with respect to its intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

	Subject Device	**Predicate Device**
Device Name	**XSense Cryoablation System with CryoProbes**	**Ice Cure Family Cryoablation System (IceSense™3, ProSense™, and MultiSense™)**
510(k) Number	K240892	K183213
Product Code	GEH	GEH
Device	Cryotherapy system	Cryotherapy system
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.
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 with an imaging device such as an ultrasound to provide real-time	IceCure Family (IceSense™3, ProSense™, and MultiSense™) cryoablation system is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. It 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 prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications:

	Subject Device	Predicate Device
Device Name	**XSense Cryoablation System with CryoProbes**	**Ice Cure Family Cryoablation System (IceSense™3, ProSense™, and MultiSense™)**
	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 -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.	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 (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth). General Surgery (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. 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. Ablation of breast fibroadenomas). Thoracic Surgery (ablation of arrhythmic cardiac tissue and cancerous lesions).

	Subject Device	**Predicate Device**
Device Name	**XSense Cryoablation System with CryoProbes**	**Ice Cure Family Cryoablation System (IceSense™3, ProSense™, and MultiSense™)**
	• Thoracic Surgery - ablation of arrhythmic cardiac tissue and cancerous lesions. • Proctology - ablation of benign or malignant growths of the anus and rectum and hemorrhoids.	Proctology (ablation of benign or malignant growths of the anus and rectum and hemorrhoids). The system may be used with imaging device like ultrasound to provide realtime visualization of the cryosurgical procedure. MultiSense™ System is indicated for three probe configuration only.
Use Environment	Professional healthcare environment	Professional healthcare environment
System Components	The system is comprised of three main subsystems: XSense (console) CryoProbes External dewar Optional accessories: Introducer Holder	The system is comprised of three main subsystems: ProSense (console) CryoProbes External dewar Optional accessories: Introducer Holder
Screen	Touch Screen mounted on the system's articulated arm. Tilt, swivel options and adjustable positioning. Screen size: 15.6"	Touch Screen mounted on the system. Tilt and swivel options. Screen size: 15.6"
Cooling System	Internal dewar of LN2	Internal dewar of LN2
Operating modes	• Freeze • Thaw • Extraction • Pause • Stick Automatic/Manual/ pre-programmed freezing cycles	• Freeze • Thaw • Extraction • Pause Automatic/Manual/pre-programmed freezing cycles
Procedure track record	Yes	Yes
Number of CryoProbes	1 CryoProbe	1 CryoProbe for ProSense™; 3 CroProbes for MultiSense™

	Subject Device	Predicate Device
Device Name	**XSense Cryoablation System with CryoProbes**	**Ice Cure Family Cryoablation System (IceSense™3, ProSense™, and MultiSense™)**
controlled by the device		
CryoProbe pretest	Yes	Yes

As described in the comparison table above, the subject XSense Cryoablation System with CryoProbes has the same intended use and indications for use, similar technological characteristics, and principles of operation as its predicate device. This is supported by performance testing deemed as required. Consequently, the technological differences between the XSense Cryoablation System with CryoProbes and its predicate device do not raise any new issues of safety or effectiveness.

1.4 Conclusions:

The XSense Cryoablation System with CryoProbes is substantially equivalent in terms of safety and effectiveness for requested indications for use to its predicate device, the ProSense™ Cryoablation System that was already cleared as part of the IceCure Medical Ltd's Family Cryoablation System (IceSense™3, ProSense™, and MultiSense™) (K183213).