December 20, 2019

IceCure Medical LTD.
% Zvi Ladin
Principal
Boston MedTech Advisors Inc.
990 Washington Street
Suite #204
Dedham, Massachusetts 02026

Re: K183213
Trade/Device Name: IceCure Family Cryoablation System (IceSense 3, ProSense, MultiSense)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: November 20, 2019
Received: November 21, 2019

Dear Zvi Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183213

Device Name
IceCure Family Cryoablation System

Indications for Use *(Describe)*
The 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:

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).
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 real-time visualization of the cryosurgical procedure.
MultiSense™ System is indicated for three probe configuration only.

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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1. 510(K) SUMMARY

IceCure's Family Cryoablation System

Name and Address of Applicant:

IceCure Medical LTD.

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Elisabeth Sadka, VP RA QA clinical

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Contact Person and Phone Number:

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Date Prepared: December 19, 2019

Name of Device

Trade/Proprietary Name: IceCure Family (IceSense™3, ProSense™ and MultiSense™) Cryotherapy Systems

Common Name: Cryosurgical unit and accessories

Classification Name: Cryosurgical unit and accessories (21 C.F.R. § 878.4350)

Product Code: GEH

Manufacturing Facility

IceCure Medical LTD.

Haeshel 7, Caesarea I.P. 3079504, Israel

Predicate Devices

The IceCure Family of Cryotherapy Systems is substantially equivalent to the cleared IceSense™3 System (K102360) and the cleared Galil Medical Seednet family (K052530).

Intended Use / Indications for Use

The 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:

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).

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 real-time visualization of the cryosurgical procedure.

MultiSense™ System is indicated for three probe configuration only.

Technological Characteristics

The IceCure Family of cryotherapy devices includes the IceSense™3 single-probe system (cleared under 510(k) #K102360 and rebranded as ProSense™), and MultiSense™ – a new system that accommodates up to three cryoprobes operating in parallel. The systems are used to destroy unwanted tissue by application of extreme cold to the selected sites. The devices deliver cold temperatures to targeted tissue by pressurized liquid nitrogen closed system and a disposable cryoprobe. Various cryoprobes are available.

The devices consist of a main chassis for the cooling system, a controller, a touch screen, a foot pedal and a cryohandle that controls the system and holds the probe.

Safety measures of the system include alarms, safety valve, emergency button and automatic abortion of the procedure in case of technical malfunction.

Comparison with the Predicate Device

Cryoablation is the fundamental technological principle for both the subject IceCure Family of cryotherapy devices and the predicate IceSense™3 System (K102360) and Galil Medical Seednet family (K052530). The subject and marketed predicate devices are used to ablate unwanted tissue by application of extreme cold.

The subject and predicate devices are based on the same technological principles:

- Delivery of cryogen from a dewar to a cryoprobe tip
- Application of cryogen to ablate (freeze) the unwanted tissue
- Heat transfer at the tip of the cryoprobe for quick release of the probe
- User-controlled (trigger/foot pedal) to release cryogen
- Software activated Controller

ProSense™ is a mere rebranding of the cleared IceSense™3 single-probe system (K102360). Therefore, the ProSense™ System has the same hardware and software components as the IceSense™3 System. Hardware and software changes introduced since the device was originally cleared on November 29, 2010, were analyzed following FDA's Guidance Documents – "*Deciding When to Submit a 510(k) for a Change to an Existing Device*" (K97-1) dated January 10, 1997 and "*Deciding When to Submit 510(k) for a Software Change to an Existing Device*," dated October 25, 2017. All changes were determined not to require new 510(k) premarket notifications and were

therefore documented and released based on the company's standard operating procedures. This submission includes the current configuration of the system.

The MultiSense™ System has the same principle of operation and technological features as the single-probe IceSense™3 (K102360) and the multi-probe Galil Medical Seednet (K052530) systems. It can accommodate up to three cryoprobes operating in parallel.

The submission was focused on two key elements:

- IceCure Medical's multi-probe system design is similar to the Galil Medical Seednet (K052530) predicate.
- Streamline the Indications for Use of the IceCure Family cryoablation system in accordance with those of the predicate devices.

	IceCure Family	**IceSense3**	**Seednet family**
510k Number	K183213	K102360	K052530
Company	IceCure Medical, Ltd.	IceCure Medical, Ltd.	Galil Medical
Device	Cryotherapy system	Cryotherapy system	Cryotherapy system
Intended use	The system is intended for cryogenic destruction of tissue during surgical procedures.	The IceSense3 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	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	The IceSense3 System is intended for cryogenic destruction of tissue during surgical procedures. It is indicated for use as a cryosurgical tool in a number of specific fields which include the following: <u>Urology</u> The system may be used to ablate prostatic tissue. The system may be used for the ablation of prostate tissue in cases of prostate cancer and	The system is intended for cryogenic destruction of tissue during surgical procedures. The 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 prostate and kidney tissue, liver

	application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. 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 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	benign prostatic hyperplasia Oncology The system may be used for ablation of cancerous or malignant tissue. The system may be used for ablation of benign tumors. The system may be used for palliative intervention. Dermatology The system may be used for the ablation or freezing of skin cancers and other cutaneous disorders. Gynecology The system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia. General Surgery The system may be used for the 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, ablation of breast fibroadenoma. The system may be used for the destruction of warts or lesions. The system may be used for the palliation of	metastases, tumors, skin lesions, and warts. The 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) 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 hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal 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, hemorrhoids, 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).

	of the oral cavity, rectum, and skin. Ablation of breast fibroadenomas). Thoracic Surgery (ablation of arrhythmic cardiac tissue and cancerous lesions). 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 real-time visualization of the cryosurgical procedure. MultiSense™ System is indicated for three probe configuration only.	tumors of the oral cavity, rectum, and skin. Thoracic Surgery The system may be used for the ablation of arrhythmic cardiac tissue. The system may be used for the ablation of cancerous lesions Proctology The system may be used for the ablation of benign or malignant growths of the anus and rectum. The systems may be used for the ablation of hemorrhoids. The system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure	Thoracic surgery (ablation of arrhythmic cardiac tissue cancerous lesions) Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids) The system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure
Cooling system location and refrigerant	Internal small [1 or 3] dewar(s) of liquid nitrogen. [1 or 3] dewar(s) used per procedure	Internal small dewar of liquid nitrogen. 1 dewar used per procedure	Internal cylinders of argon.
Thawing	Active thawing: nitrogen gas is heated by an electrical heating element. Reaching up to 35 degrees Celsius.	Active thawing: nitrogen gas is heated by an electrical heating element. Reaching around 35 degrees Celsius.	Active thawing: electric element or helium gas reaching 35 degrees Celsius.
Operating mode	Freeze, thaw, active thaw. Manual/pre-programmed freezing cycles	Freeze, thaw, active thaw. Manual/pre programmed freezing cycles	Freeze, low freeze, active thaw, off, stick
Parameters controlled by the user	Automatic or manual treatment mode; freeze or thaw time and active thaw mode. Operated from the touch screen control panel, and in addition for the IceSense™3 model only: the cryohandle buttons or the foot pedal	Automatic or manual treatment mode; freeze or thaw time and active thaw mode. Operated from the touch screen control panel, the cryohandle buttons or the foot pedal.	Probe temperature, freeze thaw stick and active thaw mode. Operated from the probe handle buttons, remote control unit.

Software controls	Valves, pump, heaters	Valves, pump, heaters	Valves, pump, heater
Parameters monitored by the software	The controller constantly monitors the status of: Microswitches, pressure and flow gauges, temperature sensors, buttons.	The controller constantly monitors the status of: Microswitches, pressure and flow gauges, temperature sensors, buttons.	The controller constantly monitors the status of: Gauges, temperature sensors, buttons.
System display	Online display: time, mode, status, messages, errors.	On line display: time, mode, status, messages, errors.	On line display: time, pressure, temperature, status, errors, messages.
Procedure track record	Yes	Yes	Yes
Number of probes controlled by the device	1 probe for ProSense™; 3 probes for MultiSense™	1 probe	1-5 probes
Probes characteristics	2.4 mm, 3.4 mm pencil or trocar tips, for small or medium, elliptical or spheric iceball. Shaft lengths for 2.4 mm probes include 124 mm and 134 mm; Shaft lengths for 3.4 mm probes include 127 mm, 140mm, and 185 mm. Made from 304 and 316 stainless steel.	2.0 mm, 2.7 mm, 3.0 mm, 3.4 mm sharp or blunt tips, for small or medium iceball. Made from 304 and 316 stainless steel.	1.5 mm, 2.0 mm, 3.2 mm, 3.4 mm, 5.0 mm, 6.0 mm for small medium or large iceball, sharp or blunt and surface probes. Made from 304 and 316 stainless steel.
Probe connection to the system	Probe is screwed to the handle	Probe is screwed to the handle	Quick connection of the pipe to the system or screwing the probe to the handle
Safety measures	Alarms, pretest, microswitch. Safety valve, pressure relief valves, Emergency stop button. Automatic abortion of the procedure in case of technical malfunction. One dewar content is for up to 15 minutes of continuous operation of freeze.	Alarms, pretest, microswitch. Safety valve, pressure relief valves, Emergency stop button. Automatic abortion of the procedure in case of technical malfunction. One dewar content is for up to 16 minutes of continuous operation of freeze.	Emergency stop button Safety valve, pressure relief valves, Emergency stop button, alarms.

Screen	Touch Screen mounted on the system. Tilt and swivel as needed	Touch Screen mounted on the system. Tilt and swivel as needed	Screen mounted on the system. Tilt and swivel as needed
Dimensions	Height: 120cm/47.24” Depth: 50cm /19.68” // 70 cm / 27.56” Width: 50 cm /19.68” Weight: 70 Kg / 154 lb (with 1 dewar) // 150 Kg / 330 lb (with 3 dewars)	Height: 120cm/47.24” Depth: 50cm /19.68” Width: 50 cm /19.68” Weight: 70 Kg / 154 lb	Height: 58” Depth: 34” Width: 23” Weight (without gas cylinders): 265 lb.
Cryoprobe pretest	Yes	Yes	Yes
Use Environment	Hospital - operating room Office procedure	Hospital - operating room Office procedure	Hospital - operating room Office procedure

Performance Data

Performance data were provided in support of the substantial equivalence determination. System was tested for conformance with relevant safety and performance standards, such as electrical testing, electromagnetic compatibility and software validation and verification, formulated in the device specifications. In all instances, the systems functioned as intended and the performance observed met acceptance criteria for all tests.

Sterilization

The IceCure Family cryoablation system accessories (probes, introducers and temperature sensor) are all sterilized utilizing an Ethylene Oxide sterilization cycle validated in accordance with ISO 11135 - Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.

Biocompatibility

The biocompatibility evaluation of patient contacting materials of the IceCure Family cryoablation system accessories was conducted in accordance with FDA’s “Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, ”Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process””.
Biocompatibility testing was not required as there were no changes in patient contacting materials.

EMC and Electrical Safety

Electromagnetic compatibility (EMC) and electrical safety (ES) of the IceCure Family cryoablation system were tested and determined to be compliant with the following standards:

- ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Bench testing

Bench testing focused on demonstrating the performance of the MultiSense system using multiple probes. The performance of the MultiSense devices was found to be similar to that of the predicate devices IceSense™3 System (K102360) and Galil Medical Seednet family (K052530). Specifically, testing documented that in the range of up to 15 minutes freeze, the probes can create an iceball of at least 40 mm diameter for a single probe, and 94 mm for a three-probe system. Performance testing included testing of the shaft temperature during freeze, thaw and warm phases. Results demonstrated that temperatures along the shaft remained within the device's specifications during all phases. The time change of iceball size and probe tip temperature were similar for the candidate and predicate devices. Iceball isotherm measurements were conducted and the results met the device's specifications.

Performance Testing - Clinical

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

Substantial Equivalence

The IceCure Family devices are as safe and effective as the cleared IceSense™3 System (K102360) and the cleared Galil Medical Seednet family (K052530).

The IceCure Family devices have the same intended uses and indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the IceCure devices and their predicate devices do not raise different issues of safety or effectiveness. Performance data demonstrate that the IceCure devices are as safe and effective as the cleared IceSense™ System (K102360) and the cleared Galil Medical Seednet family (K052530).

Thus, the IceCure Family of cryotherapy systems is substantially equivalent to its predicate devices.