November 30, 2018

Somnetics International, Inc.
% Melinda Swanson
Regulatory Consultant
Bluebird Consulting, LLC
100 NE 2nd St. #340
Minneapolis, Minnesota 55413

Re: K180388
Trade/Device Name: Transcend 365 miniCPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: Class II
Product Code: BZD
Dated: October 26, 2018
Received: October 30, 2018

Dear Melinda Swanson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180388

Device Name
Transcend 365 miniCPAP Auto System

Indications for Use *(Describe)*

The 'Transcend 365 miniCPAP Auto System' provides positive airway pressure to support treatment of adults over 66 pounds (30 kg) with Obstructive Sleep Apnea (OSA). The device is intended for home and hospital/institutional use. The integrated humidifier provides humidification of air delivered from the Transcend 365 devices. The use of the humidifier is optional.

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

510(k) Number: K180388 **Date Prepared:** November 13, 2018

Submitter/Manufacturer	Somnetics International, Inc. 33 5th Ave NW, Suite 500 New Brighton, MN 55112 Establishment Registration # 3008770104
Submission Correspondent	Melinda Swanson Regulatory Consultant Telephone: 612-308-4500 Email: melinda@bluebirddevice.com
Trade Name	Transcend 365 miniCPAP Auto System
Common/Usual Name	Non-continuous ventilator
Classification	Ventilator, Non-continuous (Respirator) 21 CFR 868.5905, Class II
Product Code	BZD
Predicate Devices	Somnetics International, Inc.: • Transcend Auto (K132127) • Transcend Heated Humidifier (K131388) Neither predicate device has been subject to a recall
Reference Device	PARI Innovative Manufacturers, Inc. PARI Hydrate V (K072982)

Device Description

The Transcend 365 miniCPAP Auto System (Transcend 365) is a new member of Somnetics' family of devices used to treat obstructive sleep apnea which includes the Transcend Auto and Transcend Heated Humidifier devices and accessories cleared via K132127 and K131388. The Transcend 365 utilizes the same blower and the same algorithm as the Transcend Auto for respiratory event detection and therapy for sleep disordered breathing events. The Transcend 365 includes the following main modifications:

- Integrated CPAP and humidification system
- Modifications from predicate Transcend Auto device
  - Graphic LCD interface vs LED in predicate
  - Housing design

    - Updated air inlet filter
    - Use of a standard 22-mm connection port for air hose attachment
    - Integrated heated humidifier with water reservoir attached with magnets
- Integrated humidifier uses Capillary Force Vaporization™ (Vapore) technology
    - Wick to a ceramic heater vaporizes water (instead of continuous heating with a heater plate)
    - Similar to PARI Hydrate V (K072982); same supplier (Vapore)
    - Allows for a smaller water reservoir and footprint

The Transcend 365 is a microprocessor-controlled, blower-based system that generates positive airway pressure to support treatment of obstructive sleep apnea. It utilizes a differential pressure sensor connected to an internal pneumotach positioned in the airstream to determine flow levels. When interfaced with a mask though use of a 22 mm breathing hose, this flow signal, coupled with pressure sensing, is used to monitor breathing and adjust pressure. The system provides fixed or auto-adjust pressure from 4 to 20 cmH_2O above the ambient atmospheric pressure to a patient's oral/nasal airway.

The humidifier uses Capillary Force Vaporization technology similar to that used in the PARI Hydrate V (Humidifier, Respiratory Gas (Direct Patient Interface); 868.5450, Product Code BTT) cleared under K072982. Water is drawn from a reservoir by a wick to a ceramic heater, which vaporizes the water resulting in comparable humidification output to the predicate devices. There is no heater plate and the water reservoir is not heated. Several humidification levels are available, with higher settings increasing the amount of water vapor. The humidifier is attached to the lower portion of the PAP through the use of magnets.

It includes the following components and accessories, which are all single patient reusable:

- Filter Media
- P10 Battery
- Transcend 365 miniCPAP Unit
- USB cable*
- Heater Cartridge
- Wick
- Reservoir
- Power supply PSA3
- US 2-prong power cord

Indications for Use

The 'Transcend 365 miniCPAP Auto System' provides positive airway pressure to support treatment of adults over 66 pounds (30 kg) with Obstructive Sleep Apnea (OSA). The

device is intended for home and hospital/institutional use. The integrated humidifier provides humidification of air delivered from the Transcend 365 devices. The use of the humidifier is optional.

Both the subject and the predicate devices have the same intended use for the treatment of OSA. The Indications for Use statement for the Transcend 365 is not identical to the predicates; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness relative to the predicate.

Comparison of Technological Characteristics with the Predicate Device

At a high level, the Transcend 365 utilizes the same blower and the same algorithm as the Transcend Auto for respiratory event detection and therapy for sleep disordered breathing events. The subject and predicate device share the same intended use, same operating principal, and are manufactured and packaged with similar processes. The substantial equivalence comparison is provided below.

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
Regulatory Classification					
510(k) Number	NA	K132127	K131388	K072982	NA
Product Code	BZD	BZD	BTT	BTT	Identical to Primary Predicate
Regulation Number	868.5905	868.5905	868.5450	868.540	Identical to Primary Predicate
Regulation Name	Ventilator, non-continuous (respirator)	Ventilator, non-continuous (respirator)	Respiratory gas humidifier	Respiratory gas humidifier	Identical to Primary Predicate
Intended Use and Indications for Use					
Indications for Use	The 'Transcend 365 miniCPAP Auto System' provides positive airway pressure to	The Transcend Auto provides positive airway pressure for treatment of obstructive sleep	The Transcend Heated Humidifier is indicated for the humidification	The Hydrate V is a Respiratory Gas Humidifier which provides heated	Identical Intended Use: Intended to treat patients with OSA with an option for

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
	support treatment of adults over 66 pounds (30 kg) with Obstructive Sleep Apnea (OSA). The device is intended for home and hospital/ institutional use. The integrated humidifier provides humidification of air delivered from the Transcend 365 devices. The use of the humidifier is optional.	apnea (OSA) in adults weighing over 66 pounds (30 kg). The device is intended for home and hospital/ institutional use.	of the air delivered from a compatible Transcend positive airway pressure therapy device. The Humidifier is intended for single patient re-use in the home environment and in a hospital/institutional environment. The Humidifier is for use only as recommended by a physician.	evaporated water content to dry breathing gases using Capillary Force Vaporization technology. A breathing circuit is used to deliver the heated and humidified gas to the patient.	providing humidification. Indication for Use: Similar to predicate devices. Slight modification to incorporate the intended use of the integrated humidifier.
Pressure Delivery					
Fixed	Yes	Yes	NA	NA	Identical feature to primary predicate
Auto-adjust	Yes	Yes	NA	NA	Identical feature to primary predicate
Algorithm					
Auto-adjust	Yes	Yes	NA	NA	Algorithm is identical to primary predicate
AHI Measurement	Yes	Yes	NA	NA	Algorithm is identical to primary predicate
Ramp	Yes	Yes	NA	NA	Algorithm is identical to primary predicate

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
Expiratory Pressure Relief	Yes	Yes	NA	NA	Algorithm is identical to primary predicate
Drying Mode	Yes	Yes	NA	NA	identical feature to primary predicate
Humidifier					
Integrated	Yes	No	No	NA	Similar. Both subject and predicate devices have a method to attach a humification system.
Humidification Method	Capillary Force Vaporization™ Technology	NA	Pass over humidification through use of a heater plate	Capillary Force Vaporization™ Technology	Similar to predicate; Devices have a method for providing heated humidified air in accordance with industry standard (ISO 8185). Capillary Force Vaporization Technology is found in the reference device PARI Hydrate V (K072982)
Humidifier/PAP Connection	Humidifier is connected to PAP via magnets	PAP is slide fit into slots in top of humidifier	PAP is slide fit into slots in top of humidifier	NA	Similar. Devices have a mechanism for securing the PAP and humidifier components together as verified by component cycling testing. Change does not impact safety or effectiveness.
Humidifier Settings	0-10	NA	0-5	Designed to automatically match the gas flow rate to	Similar. Both devices deliver a range of humidity based on setting level and are

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
				provide 100% RH. Can be physician adjusted to deliver lower RH.	adjusted by the patient for comfort. Change does not impact safety or effectiveness.
Warm-up Time	NA	NA	Up to 1 hour depending on heat setting	NA	The subject and predicate device heat water using different methods. The subject device does not have a warm up time, so this does not affect safety or effectiveness. The reference device does not have a warm up time and uses the same method to heat water
Maximum Heater Plate Temperature	NA, device does not include a heater plate	NA, device does not include a heater plate	55C	NA, device does not include a heater plate	The subject and predicate device heat water using different methods. The subject device does not have a heater plate, so this does not affect safety or effectiveness.
Water Reservoir Volume	195 ml to fill line	NA	325 ml to fill line	Up to 2 L	Similar to predicate. Humidifier contains water for 8 hours
Physical Characteristics					
Dimensions	7.8 in X 3.8 in X 4.5 in	6.1 in X 3.5 in X 2.8 in	9 in X 5.5 in X 4.7 in	12.5 in X 6.0 in X 8.0 in	Dimensions are smaller than predicate humidifier which forms the footprint of the combined predicate devices. No

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
					impact on safety and effectiveness.
Weight	1.7 lbs	Less than 1 lb	2.2 lb empty; 3.1 lbs with water to max fill line	6.8 lbs	Weight is less than combined weight of combined predicate devices when used together. No impact on safety and effectiveness.
Redesigned Enclosure	Yes	No	No	NA	Similar. Made of same flame-retardant materials (VO rating). Enclosure design does not impact safety or effectiveness as demonstrated by performance testing.
Air Filter	Reusable/ replaceable inlet filter updated to include ease of replacement.	Reusable/ replaceable inlet filter	NA	Unknown	Similar. Air filter update does not impact safety or effectiveness as demonstrated by cycling testing and other performance testing. The device uses identical filter media.
Connection Port	Compatible with commercially available 22 mm breathing hoses	Universal hose adaptor required for compatibility with commercially available 22 mm breathing hoses	NA	Delivery tubes and nasal cannula	Similar. Devices are compatible with commercially available 22 mm breathing hoses (compliant with ISO 5356-1). Does not impact safety or effectiveness

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
User Interface	Color LCD menu driven user interface	• Power button • 2 LEDs Push button to activate blower and ramp	• Power button • 3 LEDs Setting adjustment knob	Keypad control	Similar. Changes are not significant and do not impact safety or effectiveness as confirmed by usability testing (60601-1-6)
Accessories Provided with Device	None	Provided with standard 6 ft hose and universal hose adaptor.	Supplied with an industry standard 6 ft hose. Compatible with commercially available 22 mm hoses and masks	Provided with a patient cable and power cord	Similar. All devices are compatible with a 22 mm air hose
Biocompatible	New heater materials. Yes; assessed and tested for biocompatibility according to ISO 10993 and 18562	Yes; assessed for biocompatibility according to ISO 10993	Yes; assessed for biocompatibility according to ISO 10993	510k summary does not indicate biocompat-ibility status	Testing and risk assessment confirm the biocompatibility of the new materials and device. Changes do not impact safety or effectiveness
Reuse/Cleaning/Sterility					
Multi-patient Use	No	Yes, following instructions for cleaning and replacing parts	No	Yes, following instructions for cleaning of the unit and patient cable. The humidification unit, water lines, and nasal cannula are for	Subject device and predicate humidifier are for single patient use only. Does not affect safety or effectiveness.

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
				single patient use	
Cleaning/ Disinfection	Distilled water using mild detergent	Distilled water using a mild detergent	Distilled water using a mild detergent	The unit and patient cable may be wiped with an alcohol solution and a clean towel.	Identical
Sterility	Components and accessories are not provided sterile or intended to be sterilized	Components and accessories are not provided sterile or intended to be sterilized	Components and accessories are not provided sterile or intended to be sterilized	Unknown	Identical
Therapy Pressure	4-20 cm H_2O	4-20 cm H_2O	Determined by compatible PAP device	Unknown	Identical to Primary Predicate
Pressure Regulation	±1 cm H_2O or 10%, whichever is greater	±1 cm H_2O or 10%, whichever is greater	Determined by compatible PAP device	Unknown	Identical to Primary Predicate
Ramp Feature	0-45 min +25% time variance	0-45 min +25% time variance	NA	Unknown	Identical to Primary Predicate
Ramp Time	0 – 45 min	0 – 45 min	NA	Unknown	Identical to Primary Predicate
Data Storage Download	Stored on device and transferred via USB to computer with desktop software	Stored on device and transferred via USB to computer with desktop software	Not applicable	Unknown	Identical to Primary Predicate. Devices use identical desktop software
Degree of Protection Against Water Ingress	IP22	IP21	IP21	IPX1	Similar. IP22 is a more rigorous test than IP21. Does not

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
					impact safety or effectiveness.
Operating Conditions					
Operating Altitude	0 to 8,000 ft	0 to 8,000 ft	0 – 8000 ft	Atmospheric pressure 700hPa to 1060 hPa	Identical
Operating Temperature	5° C (41° F) to 35° C (95° F)	5° C (41° F) to 35° C (95° F)	5° C (41° F) to 35° C (95° F)	20° C to 29° C	Identical
Operating Humidity	10 - 80% relative humidity, non-condensing	10 - 80% relative humidity, non-condensing	10 - 80% relative humidity, non-condensing	30 % – 75%	Identical
Shipping and Storage Conditions					
Shipping/Storage Temperature	-20° C (-4° F) to 60° C (140° F)	-20° C (-4° F) to 60° C (140° F)	-20° C (-4° F) to 60° C (140° F)	-40° C to 70°C	Identical
Shipping/Storage Humidity	10 - 90% relative humidity, non-condensing`	10 - 90% relative humidity, non-condensing`	10 - 90% relative humidity, non-condensing`	10% to 100%	Identical
Electrical					
Power	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Identical
Power supply	PSA3	PSA2	2-prong power cord	G.33 power cord	The predicate devices were powered separately. The power supply has been upgraded to provide enough power to operate the PAP and humidifier. Testing confirms this

Substantial Equivalence Comparison					
	Transcend 365 miniCPAP Auto	**Primary Predicate: Transcend Auto**	**Predicate: Transcend Heated Humidifier**	**Reference PARI Hydrate V**	**Comparison**
					modification does not impact safety or effectiveness.
Optional Power Supplies	Battery: 10 cell, 18.0 VDC, 5,200 mAH	Batteries: 4 cell: 14.4 VDC, 2600 mAH or 8 cell: 14.4 VDC, 5200 mAH Solar battery charger Mobile Power Adapter	No	No	Similar to primary predicate. A larger battery is required to power the CPAP with integrated humidifier. The subject device does not include a solar battery charger or mobile power adaptor as optional accessories. Does not affect safety or effectiveness since they are not necessary for device use.
IEC 60601 Classification	Class II, Type BF	Class II, Type BF	Class II, Type BF	Class II, Type BF	Identical
RTCA DO-160 Section 21 Category M	Yes	Yes	Yes	Unknown	Identical
Sound Power Level	46.2 dBA	34.6 dBA	29.1 dBA	Unknown	Similar. Tested according to 80601-2-70. Device emitted a sound power level of 46.2 dBA meeting acceptance criteria.

Performance Data

The following performance data were used in support of the substantial equivalence determination.

- Biocompatibility Assessment: The device is categorized as tissue contact of permanent (>30 days) duration. Evaluation and testing were conducted in accordance with the following standards and guidance documents:

  - ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  - FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 16, 2016
  - ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
  - ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
  - ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
  - ISO 18562-2 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
  - ISO 18562-3 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
  - ISO 18562-4 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate

- Electrical Safety and Electromagnetic Compatibility: Testing was conducted on the Transcend 365 device. The system complies with the following standards for electrical safety and EMC:
  - IEC 60601-1: Medical electrical equipment Part 1: General requirements for safety and essential performance
  - IEC 60601-1-2: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests
  - IEC 60601-1-6: Medical electrical equipment Part 1-6: General requirements for safety – Collateral standard: Usability
  - IEC 60601-1-11: Medical electrical equipment Part 1-11: Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- ISO 80601-2-70: Medical electrical equipment Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74: Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- IEC 62133: Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from then, for use in portable applications
- UL 2054 Household and Commercial Batteries
- RTCA/DO-160G:2010, Section 21, Emissions for Category M Equipment
- ISO 8185: Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems

- Software Verification and Validation: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software in this device is considered a moderate level of concern.

- Mechanical and Acoustic Testing: component cycling, pressure regulation, auto adjust functionality, sound power levels, flow, altitude testing, expiratory pressure relief, humidifier reservoir gas leakage, 20-degree spill test, out-of-water detection, humidifier runtime, and humidifier output

Results of tests and assessments did not raise new safety or efficacy questions.

Conclusion

The Transcend 365 is substantially equivalent to the predicate Transcend Auto (K132127) and Transcend Heated Humidifier (K131388). The subject and predicate devices are used for the treatment of obstructive sleep apnea. They are equivalent in terms of technology and intended use. Risk assessments, biocompatibility evaluation, software evaluation, electromagnetic compatibility and electrical safety, mechanical and acoustic testing, including compliance with recognized standards, demonstrate that any differences do not raise new questions of safety or effectiveness. The Transcend 365 is, therefore, substantially equivalent to the predicate devices.