December 15, 2023

MIR Medical International Research USA
Alessio Segreto
Quality & Regulatory Management Representative
Viale Luigi Schiavonetti 270 - cap 00173, Rome, ITA

Re: K230501
Trade/Device Name: Spirobank Oxi
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG, DQA
Dated: November 16, 2023
Received: November 17, 2023

Dear Alessio Segreto:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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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)*
K230501

Device Name
Spirobank Oxi

Indications for Use *(Describe)*

The Spirobank Oxi Spirometer and Pulse Oximeter is intended to be used by a physician or by a patient under the prescribed use of a physician.
The equipment is intended to test lung function and can perform tests in adult and pediatric patients greater than 5 years.

When used as Oximeter, the Spirobank Oxi is intended for spot-checking of functional oxygen saturation of arterial haemoglobin (SpO2) and Pulse Rate (PR) from the patient finger .

The Spirobank Oxi has been designed for use in the physician's office, in hospital, or directly by the patient to monitor her/his physical conditions at home.

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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MEDICAL INTERNATIONAL RESEARCH

510(k) Summary

I. SUBMITTER

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Contact Person: Alessio Segreto
Date Prepared: December 15th, 2023

II. DEVICE

Name of Device:	Spirobank Oxi
Common Name:	Spirometer and Pulse oximeter
Classification Name:	Spirometer and Oximeter
Regulatory Class:	II
Regulation Number	21 CFR 868.1840
Product Code	BZG, DQA

III. PREDICATE DEVICE

Company Name:	MIR – Medical International Research
Trade Name:	SPIRODOC
510(k) number:	K103530
Regulation Number	21 CFR 868.1840
Product Code	BZG, DQA

IV. DEVICE DESCRIPTION

Spirobank Oxi is a pocket-size spirometer and oximeter.
The device is made up of:

- a central unit which measures and collects information related to the state of health of the patient, using a microprocessor based system. It operates via a Bluetooth connection
- a removable sensor for the measurement of respiratory air flow and volume,
- a pulse oximetry sensor using reflective technology.

The device is powered by two AAA alkaline batteries.

Functions of the device

Spirometry: the device is equipped with a plastic mouthpiece connected to a turbine flow meter based on the infrared interruption principle. The device detects the signals generated by the turbine, and measures flow and volume. At the end of the expiration, the device calculates the respiratory parameters.

Oximetry: the device measures functional oxygen saturation of arterial haemoglobin (SpO2) and pulse rate (PR) by means of a reflective light sensor. Specifically, it uses a two-wavelength sensor to measure the indicated parameters based on light reflection principles of oxygenated blood and deoxygenated blood, which generates a photoplethysmogram. From the photoplethysmogram the device calculates SpO2 and PR

Spirobank Oxi connects via Bluetooth to a device (PC, tablet or smartphone) which allows to insert patient data, perform spirometry manoeuvres and oximetry tests, as well as display the results, including the relative graphs.

V. INDICATIONS FOR USE:

Subject device

The Spirobank Oxi Spirometer and Pulse Oximeter is intended to be used by a physician or by a patient under the prescribed use of a physician. The equipment is intended to test lung function and can perform tests in adult and pediatric patients greater than 5 years. When used as Oximeter, the Spirobank Oxi is intended for spot-checking of functional oxygen saturation of arterial haemoglobin (SpO2) and Pulse Rate (PR) from the patient finger. The Spirobank Oxi has been designed for use in the physician's office, in hospital, or directly by the patient to monitor her/his physical conditions at home.

VI. COMPARISON WITH THE PREDICATE DEVICE

	Spirodoc – (K103530) (predicate device)	Spirobank Oxi (subject device)	SE discussion
Indications for Use Statement	The SPIRODOC Spirometer and pulse oximeter is intended to be used by a physician or by a patient under the prescribed use of a physician. The device is intended to test lung function and can perform spirometry testing in adult and pediatric patients, excluding infants and neonates, and oximetry readings in patients of all ages.	The Spirobank Oxi Spirometer and Pulse Oximeter is intended to be used by a physician or by a patient under the prescribed use of a physician. The equipment is intended to test lung function and can perform tests in adult and pediatric patients greater than 5 years. When used as Oximeter, the Spirobank Oxi is intended for spot-checking of functional oxygen saturation of arterial haemoglobin (SpO2) and Pulse Rate (PR) from the patient finger. The Spirobank Oxi has been designed for use in the physician's office, in hospital, or directly by the patient to monitor her/his physical conditions at home.	Substantially Equivalent Main functions for spirometry and oximetry are the same. The environment of use is not specified for the predicate device, but is reported in the user manual of the predicate, and it's equivalent.
Product codes	BZG, DQA	BZG, DQA	Substantially Equivalent
Device principle of operations	Spirometry: Infrared base estimation of vane rotation speed, proportional to the air flow rate. Transmission Oximetry	Spirometry: Infrared base estimation of vane rotation speed, proportional to the air flow rate. Reflection Oximetry	Substantially Equivalent Spirobank Oxi meets the accuracy requirements of the Guidance document: Pulse Oximeters - Premarket Notification Submissions [510(k)s]
Type of Use	Prescription	Prescription	Substantially Equivalent

	Spirodoc – (K103530) (predicate device)	Spirobank Oxi (subject device)	SE discussion
Patient Population	Spirometry: people of all ages, excluding infants and neonates. Oximetry: people of all ages.	Spirometry and Oximetry: people of all ages, excluding children younger than 5 years.	Substantially Equivalent. Patient population of the subject device include adult and pediatric patients greater than 5 years. This difference does not affect safety and effectiveness.
Use Environment	Spirodoc has been designed for use in the doctor's office, in a hospital or directly by the patient to monitor her/his physical conditions during routine daily activities.	Spirobank Oxi has been designed for use in the doctor's office, in a hospital or directly by the patient to monitor her/his physical conditions at home	Substantially Equivalent.
Single Patient Use	No	No	Substantially Equivalent.
System Components and Accessories	USB Cable, Noseclip, Paper Mouthpiece, Reusable Turbine, Disposable Turbine and Reusable Oximetry Sensor.	Reusable Turbine and Plastic Mouthpiece.	Substantially Equivalent.
Measured parameters: Spirometry	Spirometry: it calculates more than 20 parameters (see below) Best FVC, Best FEV1, Best PEF, FVC, FEV1, FEV1/FVC, FEV1/VC, PEF, FEF2575, FEF 25, FEF50, FEF75, FEV3, FEV3/FVC, FEV6, FEV6%, FET, EVol, FIVC, FIV1, FIV1/FIVC, PIF, MVVcal, VC, EVC, IVC, IC, ERV, TV, VE, RR, tI, tE, TV/tI, tI/tTot, MVV, ELA.	Spirometry: it calculates more than 20 parameters (see below): Best FVC, FEV1, PEF, FVC, FEV1, FEV1/FVC, FAV1/VC, PEF, FEF2575, FEF25, FEF50, FEF75, FEV3, FEV3/FVC, FEV6, FEV6%, FET, Evol, FIVC, FIV1, FIV1/FIVC, PIF, MVVcal, ELA	Substantially Equivalent.

	Spirodoc – (K103530) (predicate device)	**Spirobank Oxi (subject device)**	**SE discussion**
Measured Parameters: Oximetry	Oximetry: spot checking and monitoring parameters (see below): %SPO2 min, %SPO2 max, BPM min, BPM max, %SPO2 mean, BPM mean, T Total, T Analysis, T<90%, T<89%, T<88%, T<87%, Ev%SPO2<89, Δ Index, T<40BPM, T>120BPM, Ev<40BPM, Ev>120BPM, %SPO2 start, %SPO2 end, BPM end, %SPO2 Base, BPM start, T Baseline, T Walking, T Recovery, Distance, T2%Δ SPO2, T4%Δ SPO2, Predicted, Predicted min, % Predicted, %Predicted min, AUC/Distance*, Dyspnea Base, Dyspnea End, Dyspnea CHG, Fatigue Base, Fatigue End, Fatigue CHG, Diastolic Base, Systolic Base, Diastolic Fine, Systolic Fine, Steps, VMU**, O2-GAP***, O2, SPO2 Base, BPM Base, ODI, Mean Dur. Desat., Tot Desaturat., Longest Desat., Desatur. Peak, BPM Index, Mean Desaturat, Mean Drop, Max Drop, BPM Variation, NOD4%, NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90%.	Oximetry: spot checking parameters (see below): %SpO2 min, %SpO2 max, BPM min, BPM max, %SpO2 mean, BPM mean, T Total.	Substantially Equivalent
Range of Measurement : Spirometry	Volume: 10L Flow: ± 16 L/s	Volume: 10L Flow: ± 16 L/s	Substantially Equivalent

	Spirodoc – (K103530) (predicate device)	**Spirobank Oxi (subject device)**	**SE discussion**
Range of Measurement :Oximetry	Range of measurement %SpO2: 0 – 99% Range of measurement of cardiac pulse: 30 – 254 BPM.	Range of measurement %SpO2: 70 – 100% Range of measurement of Pulse Rate: 30 – 200 BPM.	Substantially Equivalent

	Spirodoc – (K103530) (predicate device)	**Spirobank Oxi (subject device)**	**SE discussion**
Test Accuracy: Spirometry	American Thoracic Society (ATS) Statement on the "Standardization of Spirometry – 1994 Update Spirometry Volume: Volume accuracy: ± 3.0% or ± 50 mL Linearity: ±3% Repeatability: ±0,05L or ±3% Expiratory Impedance: <0,15 kPa/(L/s) Spirometry Flow: Flow accuracy: ± 5% or ± 200 mL/s Dynamic resistance at 12 L/s: <0.5 cm H_2O/L/s Linearity: ± 5% or ± 0.17L/s Resistance to Flow: <0.36 kPa/(L/s) Frequency response: ± 12% or ± 0.25L/s	American Thoracic Society (ATS) Statement on the "Standardization of Spirometry – 2019 update Spirometry Volume: Volume accuracy: ± 2.5% Linearity: ±2.5% Repeatability: ±2.5% Expiratory Impedance: <0,15 kPa/(L/s) Spirometry Flow: Flow accuracy: ± 5% or ± 200 mL/s Dynamic resistance at 12 L/s: <0.5 cm H_2O/L/s Linearity: ± 5% or ± 0.17L/s Resistance to Flow: <0.36 kPa/(L/s) Frequency response: ± 12% or ± 0.25L/s	Substantially Equivalent Spirobank Oxi meets the accuracy requirements of the current ATS guidelines.

	Spirodoc – (K103530) (predicate device)	**Spirobank Oxi (subject device)**	**SE discussion**
Test Accuracy: Oximetry	SpO2 ± 2% between 70-100% Pulse Rate: ± 2 BPM or 2% whichever is greater	SpO2 70% - 100 %: ± 1.90% 70% - 80 % ± 2.33% 80% - 90 % ± 1.71% 90% -100 % ± 1.49% Pulse Rate: ± 3%	Substantially Equivalent Spirobank Oxi meets the accuracy requirements of the Guidance document: Pulse Oximeters - Premarket Notification Submissions [510(k)s]
Data transmission	USB or Bluetooth	Bluetooth 4.0	Substantially Equivalent Spirobank Oxi has been qualified according to Bluetooth SIG. Spirobank Oxi data transmission integrity has been thoroughly tested.

	Spirodoc – (K103530) (predicate device)	Spirobank Oxi (subject device)	SE discussion
Materials	Main parts and materials • Case: PC+ABS: - LUPOY® HP-5004I (white parts), LUPOY® GP-2102 (orange part) • Turbine: polycarbonate resin - Makrolon 2805 (orange part) , LEXAN 121R (deflector) • Mouthpiece: plastic (PP) • Oximeter sensor: Polymers and Plastic Resins –HYSOL MG18 CLEAR	Main parts and materials • Case: plastic (PC + ABS - Bayblend) • Turbine: polycarbonate resin - Makrolon 2805 (orange part) , LEXAN 121R (deflector) • Mouthpiece: plastic (PP) • Oximeter sensor: Transaprent Polyamide (Trogamid)	Case: different materials. Turbine: same Mouthpiece: same Oxymetry finger sensor: different materials. Biocompatibility tested in accordance with ISO 10993-1. Mechanical characteristics were tested in accordance with IEC 60601-1.
User interface	Touch screen LCD display, resolution 160 x 80 or PC or mobile phone screen via Bluetooth Connection	Smartphone, PC or tablet display via Bluetooth Connection	Substantially Equivalent
Power supply	Two Rechargeable AAA LiPo batteries	Two alkaline AAA batteries	Substantially Equivalent
Weight	150 g (including batteries)	60.7 g (including batteries).	Substantially Equivalent
Dimensions	48 (W) x 148 (L) x 25 (H) mm	49 (W) x 109(L) x 21 (H) mm	Substantially Equivalent
Data storage	Up to 10000 measurements	>1000 measurements, depending on the memory of the smartphone	Substantially Equivalent

The subject device, Spirobank Oxi, and the Predicate, Spirodoc - K103530, have the following key similarities:

- Both devices have the same intended use as spirometer and oximeter;
- Both devices have the same technological characteristics with respect to spirometry: the principle of operation is the same: the air flow passes through the turbine and makes the blade of the turbine rotate. Rotation speed which is in linear relationship with the air flow rate is measured by photodetectors.

The different technological characteristics do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA.

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

Biocompatibility testing
Biocompatibility of the materials has been tested for cytotoxicity, irritation, and sensitization according to ISO 10993-1: 2009, following FDA's guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". Results of the tests show that materials are biocompatible.
Also, the standards ISO 18562 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - part 1, 2 and 3, have been followed to assess the biocompatibility evaluation of breathing gas pathways.

Electrical safety and electromagnetic compatibility (EMC)
Electrical Safety and Electromagnetic compatibility testing was conducted in accordance with EN 60601-1:2005 + Amd 2012 (identical to IEC 2005 + Amd 2012) and EN 60601-1-2:2015 (identical to IEC 60601-1-2:2014). In addition, the following FDA guidance documents were to directly applicable to the Spirobank Oxi:

1. Electromagnetic Compatibility (EMC) of Medical Devices, June 2022

2. Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff, August 2013

3. Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff, November 2014

The results demonstrates that the Spirobank Oxi complies with the guidelines and standards referenced and that it performs within its specifications.

Spirometry Testing
Performance test has been carried out on the bench according to the American Thoracic Society (ATS) Statement on the "Standardization of Spirometry – 2019". The test has been conducted in MIR facilities using a Pulmonary Waveform Generator. In accordance with ATS 2019, the subject device was also tested and demonstrated conformance to standards ISO 26782:2009 – Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans and ISO 23747:2015 – Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans.

Pulse rate accuracy
Testing was conducted in accordance FDA guidance for Pulse Oximeters and ISO 80601-2-61: Medical

Electrical Equipment – Particular requirements for basic safety and essential performance of pulse oximeter equipment. The accuracy of Spirobank Oxi pulse rate measurements has been evaluated using a functional tester which allows evaluation of pulse rate over the claimed display range for the device (30 – 200 bpm). The maximum absolute error measured during the tests was as high as 3bpm, at a simulated pulse rate of 200 bpm. The results demonstrate conformance to the standard and that the Spirobank Oxi performs within its specifications.

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

Cybersecurity Testing and Validation were conducted and documented in accordance to FDA Guidance, Postmarket Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff, December 2016.

Human Factor testing
Human Factors testing has been carried out to assure that the subject medical device is safe and effective for the intended users, uses, and use environments. Human factor testing has been performed following the recommendation of the FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices", February 2016.

Cleaning and Disinfection
Validation of Cleaning methods used for the SpirobankOxi were validated in accordance with FDA Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff, Issued March 2015.

Clinical Performance Testing
Determination of substantial equivalence for Oximetry is based on assessment of clinical data, as per Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff (2013) and ISO 80601-2-61:2017 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
The data have been collected from a single arm desaturation study conducted in the US, at the Clinimark Desaturation Laboratory (Site ID# 001, , Louisville, CO 80027, USA).

Primary Endpoint: evaluation of pulse oximeter accuracy of Spirobank Oxi using data from desaturation study in healthy volunteers, according to the procedure reported in Annex EE of ISO 80601-2-61:2017 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Study Population: the data was collected from 10 healthy volunteers (five males and five females). The skin pigmentation / tones ranged from light to dark meeting the requirement of at least 2 darkly pigmented or 15 % of the subject pool whichever is larger.

The Spirobank Oxi pulse oximetry system was placed on the finger of the subject to evaluate the SpO2

accuracy performance during steady state non-motion conditions. RED and IRED signals were collected from the subject device. A Clinimark Control Pulse Oximetry system was also placed on the subject to evaluate the stability of the draws and the real time oxygen saturation status. The gas mixture was controlled to various levels of induced hypoxia resulting in stable oxygen saturation plateaus between 100% and 67% SaO2. Arterial blood samples were drawn during simultaneous data collection from the control pulse oximeter and from the subject device. The blood was immediately analyzed by Reference CO-Oximetry providing functional SaO2 for the basis of the SpO2 accuracy comparison. This value is obtained as the mean of the SaO2 values measured by Radiometer ABL 80 Flex OSM and Instrumentation Laboratory IL 682. The Sp02 values of each volunteer were then calculated for the subject device by applying its calibration function using the RED and IRED signals collected during the desaturation study.

The study met the primary endpoint. The SpO2 values measured by subject device were compared with the SaO2, using the formula for determination of root mean square difference (Arms) indicated in the ISO 80601-2-61:2017. The following Arms were obtained:

Total Arms	1.9004
Arms 90%-100%	1.4861
Arms 80%-90%	1.7059
Arms 70%-80%	2.3315

The SpO2 Accuracy analysis for the Spirobank Oxi resulted in an Arms value of 1.9004, thus complying with the ISO 80601-2-61 and the FDA Guidance.

There were no adverse events and complications.

Summary
Based on the clinical performance as documented in the clinical study, the Spirobank Oxi device was found to have a safety and effectiveness profile as the predicate device.

VIII. Conclusions

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Spirobank Oxi device performs as intended in the specified use conditions. The clinical data demonstrate that the Spirobank Oxi device performs comparably to the predicate device that is currently marketed for the same intended use.
Based on these results, the Spirobank Oxi device is substantially equivalent to the predicate device.