July 11, 2025

CAIRE Inc.
Ted Vlahopoulos
Sr. Regulatory Specialist
2200 Airport Industrial Drive, Ste 500
Ball Ground, Georgia 30107

Re: K250671
Trade/Device Name: FreeStyle Comfort (AS200 / FreeStyle Comfort)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: May 8, 2025
Received: June 30, 2025

Dear Ted Vlahopoulos:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250671

Device Name
FreeStyle Comfort (AS200 / FreeStyle Comfort)

Indications for Use *(Describe)*

The FreeStyle Comfort Oxygen Concentrator can deliver concentrated oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. FreeStyle Comfort may be used in the home, institution, and transport modes.

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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FreeStyle Comfort - 510(k) Summary

Submitter:

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Registration Number: 3004972304

Contact person:

Ted Vlahopoulos

Senior Regulatory Specialist

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Date Prepared: May 12, 2025

Device Trade Name:	FreeStyle® Comfort® Oxygen Concentrator
Common Name:	Portable Oxygen Concentrator
Classification Name:	Generator, Oxygen.
Regulation Number:	21 CFR 868.5440
Product Code:	CAW
Device Class:	Class II
Classification Panel:	Anesthesiology and Respiratory Therapy Devices

Predicate Devices:

Predicate	Referenced Predicate
Inogen Rove™ 4 Portable Oxygen Concentrator Product Code: CAW 510(k) number: K222086	Omni 3 Portable Oxygen System Proprietary Name: eQuinox™ Oxygen System, CAIRE Product Code: CAW 510(k) number: K120785

Device Description:

The FreeStyle® Comfort® is a reusable, lightweight portable oxygen concentrator weighing 5 lbs. (2.3 kg) with the lithium-ion single battery pack, and 6 lbs. (2.7 kg) with the optional lithium-ion double battery pack.

The FreeStyle Comfort's light weight and portability allow the user to receive supplemental oxygen while traveling, shopping or while at home. The FreeStyle® Comfort® complies with FAA guidelines for use on-board commercial aircraft.

The FreeStyle® Comfort® oxygen concentrator has 5 flow settings delivering up to 1050 mL of concentrated oxygen per minute. The subject device has two delivery options, autoSAT® Pulse or Fixed Minute Pulse, providing 90% (+5.5% / -3%) of concentrated oxygen. Like the predicate device, the FreeStyle® Comfort® releases a pulse of oxygen (bolus) at the beginning of inhalation by using oxygen conserving technologies. The oxygen conserving technology detects inhalation and quickly delivers a pulse of oxygen to the user. This method of oxygen delivery increases device portability, ambulation, and battery life for extended use away from the home, as compared with continuous O2 flow oxygen concentrators.

The outer enclosure of the FreeStyle® Comfort® is made of UL/CSA-approved PC/ABS plastic. The innerworkings include two alloy cylinders, each filled with molecular sieve (referred to as sieve beds), an internal piston air compressor, valves, tubing assembly, electrical wiring harness, filters, and control board. FreeStyle® Comfort® does not require sterilization and is not a single use device.

Operating Principles

The control board uses software to operate the unit. The device operating principle is a process known as Pressure Swing Adsorption, or PSA. Air is drawn into the device through the air intakes to the air compressor. Pressurized air flows from the air compressor to each of the (molecular) sieve beds in cycles. As one sieve bed is filled with pressurized air, the oxygen passes through the sieve bed. As the oxygen travels through the sieve bed, the nitrogen molecules collect on the molecular sieve. At the end of the cycle, the nitrogen is purged using enriched oxygen, then the process begins again with the alternate sieve bed (one sieve bed depressurizes while the other sieve bed is pressurized). This process continuously repeats from one sieve bed to the other, producing highly concentrated oxygen. Concentrated oxygen flows from the sieve beds to the product tank, then through sensors that measures both oxygen concentration and flow, then delivered to the patient.

AutoSAT Feature

Traditional pulse dosing supplies the same amount of oxygen delivered to the patient per minute regardless of the number of breaths taken. If the patient inhales more often, such as during physical activity like walking, the amount of oxygen delivered decreases per breath to maintain the same volume of oxygen per minute. The autoSAT (automatic titration to patient's respiratory rate) function delivers a consistent pulse dose (bolus) volume of oxygen (up to 40 breaths per minute). As breath rate increases during physical activity, the amount of oxygen delivered will stay the same per breath, which increases the volume of oxygen delivered per minute.

The autoSAT function is a default setting in the FreeStyle Comfort. The user can change the setting to traditional dosing by using the membrane touchpad to switch off the autoSAT function. During normal operation, if after more than 15 seconds the device does not detect breath inhalation, the device will automatically begin dosing @ 20 breaths per minute until breath inhalation is detected. Upon detection, the device will resume normal operation in autoSAT mode.

Inhalation Sensitivity

The FreeStyle® Comfort® offers an inhalation sensitivity mode. The user can adjust the sensitivity settings values from 1-5, where 1 is the least sensitive, 5 is the most sensitive. The sensitivity function has a default setting of >-0.1 cm H2O and a maximum adjustable range of -0.3 to -0.40 cm H2O, negative pressure (inhalation) to trigger the flow (bolus) of O2 to the user. In cases where shallow breathing cannot be detected at the device (default) sensitivity setting, the user can adjust the setting with the membrane keypad to increase inhalation sensitivity to trigger oxygen delivery at the desired flow setting.

Power Options

FreeStyle Comfort is powered with either a single or double lithium-Ion battery pack or with an external AC/DC power source (A/C wall outlet or DC vehicle). FreeStyle® Comfort® includes a built-in battery charger that will automatically recharge the battery pack when the unit is plugged into an external power source, except during use on a commercial aircraft. When an AC/DC power source is not readily available for battery recharge, the battery pack can easily be removed for quick replacement by pressing the battery release button and sliding the battery pack out from the device.

Device battery is capable of up to 8 hours of operation using the 8-cell battery, and 16 hours with the 16-cell battery, depending on the selected flow setting and user's breathing rate. The battery charge status is displayed on the keypad LCD during normal operation.

User Interface

The touch membrane keypad display allows the user to operate the device. The user can select the desired pulse dose volume and view the operating status. Once the user completes the selection process, the display screen will enter "standby" mode and then dims after 20 seconds. Pressing any button on the keypad will wake the display screen from standby mode. Oxygen delivery from the device to the user is channelled via a nasal cannula/tubing assembly, manufacturer Salter Labs (SunMed, LLC.), P/N 1600 (K911740). The end user is required to follow the cannula manufacturer's instructions for length of use, maintenance, and replacement requirements.

Keypad/Alarms

Operating information, battery, and operating status is displayed on the keypad LCD window. The subject device comes equipped with both visual and audible alarms.
The FreeStyle Comfort features the following visual and audio safety alarms:

- Low oxygen concentration
- System malfunction due to high temperature, high system pressure or compressor fault
- System malfunction due to low temperature, low pressure or fan failure
- Flow Rate failure due to obstruction of gas pathway (cannula blockage)
- Low battery (activates at 20% battery power and intensifies alarm at 5% battery power)
- Auto-dosing until warm up is complete and breath detection is activated
- After 15 seconds of no breath detected the unit shifts from autoSAT to auto-dose.

Wireless Connectivity

The FreeStyle Oxygen Concentrator utilizes Bluetooth technology that pairs the portable oxygen concentrator to a mobile device or tablet using the myCAIRE App.

The myCAIRE™ app connects patients with home care providers (DME), allowing DMEs to view usage hours and flow settings of a connected CAIRE oxygen concentrator. The system uses wireless technology (BLE) to transmit information from the concentrator to a smart device, which then sends it to the home care provider. Home care providers can assist patients by addressing device notifications and supplying recommendations for troubleshooting remotely.

myCAIRE™ shares data from CAIRE oxygen concentrators without altering settings, performance, or therapy. It is not intended for monitoring, diagnosis, or treatment. The connection only sends data to the app in raw format, decodable solely by Caire, with no Protected Health Information or Personally Identifiable Information transmitted.

Associated Accessories

The device comes equipped with a rechargeable 8-cell lithium-Ion battery pack, A/C power supply/cord, DC power supply. Optional equipment consists of a 16-cell lithium-Ion battery pack for extended use and the desktop battery charger.

The following components are included with this FreeStyle® Comfort® 510(k) submission:

- 8-cell Battery Pack, lithium-Ion
- A/C power supply/power cord and plug
- Carrying case/shoulder strap
- DC Power Supply
- User manual
- 16-cell Battery Pack, lithium-Ion
- Carry All Accessory Bag (stores the device and accessories)
- Desktop Battery Charger
- Backpack
- Spare Replacement Filters

The basic technology of the FreeStyle Comfort Oxygen Concentrator is equivalent to the FDA cleared oxygen concentrator, Inogen Rove 4 Portable Oxygen Concentrator, 510(k) reference K222086.

Photos:

FreeStyle® Comfort®

with Carrying Case

Control Panel Display/Keypad

Single & Double Battery Packs

FreeStyle Comfort Specifications	
Dimensions (with Single Battery)	10.0 x 7.3 x 3.1 in (25.4 x 18.5 x 7.9 cm)
Dimensions (with Double Battery)	11.0 x 7.3 x 3.1 in (27.9 x 18.5 x 7.9 cm)
Weight (with Single Battery Pack)	5 lbs (2.3 kg)
Weight (with Double Battery Pack)	6 lbs (2.7 kg)
Operating Nominal Sound Level***	Max 43.0 dB(A) @ 2 Maximum sound power of 51 dBA Maximum system sound pressure of 51 dBA Typical alarm sound pressure of 56.49 dBA (sound pressures measured at 1 meter per ISO 3744)
Flow Settings	Pulse Setting 1, 2, 3, 4, 5
O2 Output Setting (@20 bpm All Volumes +/- 15%)	Setting 1 - 210 mL/min Setting 2 - 420 mL/min Setting 3 - 630 mL/min Setting 4 - 840 mL/min Setting 5 - 1050 mL/min
Oxygen Concentration*	90% (+5.5% / -3%)
Oxygen Monitor	Yes
Maximum Outlet Pressure	<30 PSI
Dosing Sensitivity	> -0.1 cm H^2O (adjustable)
AC Power	100–240 VAC, 50-60Hz, 120W Max
DC Power	11–18 VDC (10 max amp)
Battery Type	Lithium Ion
Battery Capacity	Single cell: 6700 mAh; Double cell: 13400 mAh
Battery Re-Charge Time	Single Battery: 3.5 hours Double Battery: 6.0 hours
Battery Pack Durations	Single Battery Duration: Setting 2 - up to 4 hours Double Battery Duration: Setting 2 - up to 8 hours
Operating Temperature**	41°F to 104°F (5°C to 40°C)
Transportation and Storage Temp. (Unit)	-13°F to +158°F (-25°C to +70°C) up to 10000 ft (3048 m)
Transportation and Storage Temp. (Battery)	-13°F to +158°F (-25°C to +70°C) up to 10000 ft (3048 m)
Operating Altitude**	-1250 to 10,000 ft (-381 to 3048 m) (tested to 700 – 1060 hPa)
Operating Humidity	15 - 95% relative humidity (non-condensing)
Storage Humidity	0 - 90% non-condensing
Limited Warranty	See Warranty Statement

* Based on an atmospheric pressure of 14.7 psi (101 kPa) at 70°F (21°C)
** The unit will function in all environments as long as the environment is with the specified temperature and humidity ranges. Operating outside of these operational specifications can limit the concentrator's ability to meet oxygen concentration specification at higher liter flow rates. Warm up screen may continue to display until the concentrator has reached target concentration or up to 15 minutes. Continue to use unit during this time.
***Sound level measured per test method Nr. 14-1 10/2018 MDS-Hi.
The expected service life is a minimum of five years.

Intended Use:

The FreeStyle Comfort Oxygen Concentrator can deliver concentrated supplemental oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery.

The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. The device is designed for use in the home, in a vehicle, and for use during air travel.

The device is not intended for life support, nor does it provide any patient monitoring capabilities.

Indications for Use:

The FreeStyle Comfort Oxygen Concentrator can deliver concentrated oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. FreeStyle Comfort may be used in the home, institution, and transport modes.

Contraindications:

DO NOT use this oxygen concentrator until you first seek medical advice. Although oxygen is a non-addictive drug, unauthorized oxygen therapy can be dangerous. The Equipment Provider who supplies your oxygen equipment will demonstrate how to set the prescribed flow rate.

DO NOT change the flow selection unless you have been directed to do so by a licensed clinician. It is very important to select only the prescribed level of oxygen. Pulse dose mode settings must be determined for each user individually for their needs at rest, during exercise, and when traveling.

DO NOT use in the presence of flammable anesthetics.

This device should not be used without first being prescribed by a physician. In certain circumstances, the use of non-prescribed oxygen can be hazardous.

This device is not intended to be used for life support. Additional monitoring may be required for any user who is unable to communicate discomfort.

This device is not intended for use in or near magnetic resonance environments, such as MRI machines.

This device is not intended for use with a tracheotomized patient.
Some respiratory efforts of the patient might not trigger the conserving function.

Description of Use/Patient Population:

Oxygen Concentrators are intended to supply supplemental oxygen to users suffering from ailments which affect the efficiency of one's lungs to transfer oxygen in the air to their bloodstream. Oxygen concentrator use requires a physician's prescription.

This device is not intended for and has not been tested or approved for use with newborn, infant, or pediatric patient populations.

Users typically have good cognitive abilities and must be able to communicate discomfort. If the user is unable to communicate discomfort, or unable to read and understand the concentrator labeling and instructions for use, then use is recommended only under the supervision of one who can. If any discomfort is felt while using the concentrator, users are advised to contact their healthcare provider. Users are also advised to have back-up oxygen available (i.e. cylinder oxygen) in the event of a power outage or concentrator failure. There are no other unique skills or user abilities required for concentrator use.

Comparison of Technological Characteristics and Performance with Predicates.

The table below provides a side-by-side comparison of the FreeStyle Comfort User Interface elements with respect to the predicate device, the Inogen Rove 4. The user interface features are broken down by category and the elements of each category. All FreeStyle Comfort User Interface elements have been found to be substantially equivalent to that of the predicate device, refer to the comparison table below.

Subject Device - Predicate Device Comparison Table

	Subject Device: FreeStyle® Comfort®	**Predicate Device:** Inogen Rove™ 4	**Referenced Predicate Device:** eQuinox ™
510(k) No.	K250671	K222086	K120785
CFR	21 CFR 868.5440	21 CFR 868.5440	21 CFR 868.5440
Product Code	CAW	CAW	CAW
Classification	2	2	2
Rx Required	Yes	Yes	Yes
Patient Use	Adult	Adult	Adult
Intended Use	The FreeStyle Comfort Oxygen Concentrator can deliver concentrated supplemental oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. The device is designed for use in the home, in a vehicle, and for use during air travel. The device is not intended for life support, nor does it provide any patient monitoring capabilities.	The Inogen Rove 4™ is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation.	The eQuinox Oxygen System is intended for the administration of supplemental oxygen. The eQuinox Oxygen System is prescription legend required.
Indications for Use	The FreeStyle Comfort Oxygen Concentrator can deliver concentrated oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. FreeStyle Comfort may be used in the home, institution, and transport modes	Inogen Rove™ 4 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institutions, and transport modalities. The device is to be used as an oxygen supplement and is not intended to be life-sustaining or life-supporting.	The eQuinox Oxygen System is intended for the administration of supplemental oxygen.
User/Patient Interface	User Interface Panel	User Interface Panel	User Interface Panel
	LCD Display to convey information about operating status in numbers, text, and symbols.	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers, text, and symbols.
	Alarm Indicator – yellow "Alarm/Warning" triangle symbol on LCD display is to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Alarm Indicator – yellow LED on UIP above "Alarm/Warning" triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Audible ALARM (red indicator): An audible indicator and solid red light announce a reduction in oxygen concentration or power loss or interruption.

	Breath Detect Notification – Green LED on LCD Display illuminates when a breath is detected, and an oxygen pulse is triggered	Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered	Breath Detect Notification – Green LED illuminates when a breath is detected, and an oxygen pulse is triggered
	Auditory Buzzer – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Auditory Buzzer – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Auditory alarm - An audible alarm alerts you to the operating condition of the device, either a warning or failure, and confirms a valid key press.
	Air Intake Filters (2) - Patient instructed to clean the air intake filters once per week.	Particle Filter – Patient instructed to clean particle filters once per week.	Air Inlet Filter - Patient instructed to clean particle filter once per week.
	Optional accessories - Carry bag, shoulder strap, carry-all accessory bag, external battery charger	Optional accessories - Carry bag, backpack, external battery charger	Optional accessories – Travel cart, travel case, external battery charger
	myCAIRE Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	The eQuinox™ Oxygen System does not provide wireless connectivity.

Components	Electrical Power Source: AC/DC Power Adapter – Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	AC/DC Power Adapter – Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	AC/DC Power Adapter – 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.
	DC Power Cable – cord and adapter to allow for connection to 12-volt DC auxiliary port connector and barrel jack connection to concentrator.	DC Power Cable – cord and adapter to allow for connection to 12-volt DC auxiliary port connector and barrel jack connection to concentrator.	DC Power Cable – cord and adapter to allow for connection to 12-volt DC auxiliary port connector and barrel jack connection to concentrator.
	Rechargeable single or double battery (1) 96.5 W-Hr Lithium-Ion Battery Pack (8 cell). Optional Double Battery (2) 96.5 W-Hr Lithium-Ion Battery Pack (16 cell). The battery slides into the base of the device.	Battery – utilizes a 4 or 8-cell lithium-Ion battery. To attach the battery, slide it on to the base of the concentrator.	Rechargeable single or double lithium- Ion battery pack, 89 W-Hr single battery pack 12-cell battery or 95 W-Hr double battery pack 24-cell battery
	Cannula - Off the shelf 7’ nasal cannula	Cannula – Off-the-shelf 7’ nasal cannula	Cannula - Off the shelf 7’ nasal cannula

Principle of Operation	The FreeStyle® Comfort® uses software to operate the unit. The device generates oxygen through a process known as "pressure swing adsorption" or PSA. Air is drawn in through the two air intake filters to the air compressor. Pressurized air flows from the air compressor to each of the sieve beds in cycles. As one sieve bed is filled with pressurized air, oxygen passes through that sieve bed. As the air travels through the sieve bed, nitrogen molecules collect on the molecular sieve. At the end of the pressure cycle, the nitrogen is purged using enriched oxygen and then the process begins again with the alternate sieve bed (one sieve bed depressurizes, the other sieve bed is pressurized). This process will continuously repeat from one sieve bed to the other producing highly concentrated oxygen. Oxygen flows from the sieve beds to the product tank, then through sensors that measure both oxygen concentration and flow. Oxygen is delivered to the patient on a demand flow basis during the inhalation breathing cycle. The oxygen conserver technology eliminates oxygen waste during the exhalation (breathing) cycle when it is not needed. The FreeStyle® Comfort® releases a pulse of oxygen (bolus) at the beginning of inhalation by using oxygen conserving technologies. The oxygen conserving technology detects inhalation and quickly delivers a pulse of oxygen from the product tank, through the O2 filter and channeled to the user with a nasal cannula. This method of oxygen delivery is controlled with pressure sensors and software.	The Inogen Rove™ 4 Portable Oxygen Concentrator uses molecular sieve / pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced by pressure through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. Oxygen is collected in an accumulator reservoir. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Waste nitrogen is exhausted back into the room. A series of sieve beds, a manifold with precision valves, sensors, and embedded software to control the cycle are used to make the system function. Oxygen is delivered to the patient on a demand flow basis during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. The Inogen Rove™ 4 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and onto the patient. Pressure sensors and embedded software are used to control the conserving function.	The eQuinox™ uses a passive system to separate oxygen from air. Clean air flows into the eQuinox™ where it enters a compressor. Pressurized air flows from the compressor into the ATF® Concentrator Module (molecular sieve bed) where it is separated into oxygen and nitrogen components. The air separation process uses a rotary valve system in the ATF module to force air through a series of pressurized sieve beds. Through a process known as "pressure swing adsorption," oxygen molecules are collected on an absorbent material within the ATF and forced through a sieve into the product tank. The remaining nitrogen molecules are purged using a vacuum pressure cycle. Oxygen flows from the product tank through a HEPA filter and past a sensor that measures flow and concentration. A flow control valve regulates the flow of purified oxygen presented to the patient. The process is continuously repeated during operation.
Operating	Portable. For use in home, institutions, and transport modalities.	Portable. For use in home, institutions, and transport modalities.	Portable. For use in home, institutions, and transport modalities.

Environment			
Power Source	The AC/DC Power Adapter – Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	AC/DC Power Adapter – Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	AC/DC Power Adapter – 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.
	The DC Power Cable – cord and adapter to allow for connection to 12-volt DC auxiliary port connector and barrel jack connection to concentrator.	DC Power Cable – cord and adapter to allow for connection to 12-volt DC auxiliary port connector and barrel jack connection to concentrator.	DC Power Cable – cord and adapter to allow for connection to 12-volt DC auxiliary port connector and barrel jack connection to concentrator.
	Battery - Utilizes a Lithium-Ion Battery Pack (8 cell) or Optional Double Battery (16 cell). Battery attaches by sliding it on to the base of the concentrator.	Battery – utilizes a 4 or 8-cell lithium-Ion battery. To attach the battery, slide it on to the base of the concentrator.	Battery – Utilizes a 12-cell battery pack 12-cell battery or 24-cell battery pack. Battery slides into the front of the unit
Flow Control Settings	Pulse dose settings 1, 2, 3, 4, 5	Pulse dose settings 1, 2, 3, 4	Pulse dose settings 1, 2, 3, 4, 5, 6, 7, 8, 9 Continuous lpm settings 0.5, 1, 1.5, 2.0, 2.5, 3.0
Oxygen Concentration	90% +5.5% /-3% at all flow settings	87% to 96% at all flow settings	90% +5.5%/-3% at all flow settings

Oxygen Flow Rate	Fixed-Minute Pulse: Setting 1 - 210 mL per minute, 10.5 mL @20 bpm Setting 2 - 420 mL per minute, 21.0 mL @20 bpm Setting 3 - 630 mL per minute, 31.5 mL @20 bpm Setting 4 - 840 mL per minute, 42.0 mL @20 bpm Setting 5 - 1050 mL per minute, 52.5 mL @20 bp *Dose volume adjusts based on breath rate.*	Fixed Minute Pulse: Setting 1 – 210 mL per minute, 10.5 mL @20 bpm Setting 2 – 420 mL per minute, 21.0 mL @20 bpm Setting 3 – 630 mL per minute, 31.5 mL @20 bpm Setting 4 – 840 mL per minute, 42.0 mL @20 bpm *Dose volume does adjusts based on breath rate*	Fixed Minute Pulse is N/A in this device

Fixed Minute Pulse Volume (mL) Setting (Tolerance +/-15%)					
Breath Rate	1	2	3	4	5
15	14.0	28.0	42.0	56.0	70.0
20	10.5	21.0	31.5	42.0	52.5
25	8.4	16.8	25.2	33.6	42.0
30	7.0	14.0	21.0	28.0	35.0
35	6.0	12.0	18.0	24.0	30.0
40	5.3	10.5	15.8	21.0	26.3
Total Volume Per Min (mL/min)	210	420	630	840	1050

Breath rate	1	2	3	4
10	21.0	42.0	63.0	84.0
15	14.0	28.0	42.0	56.0
20	10.5	21.0	31.5	42.0
25	8.4	16.8	25.2	33.6
30	7.0	14.0	21.0	28.0
35	6.0	12.0	18.0	24.0
40	5.25	10.5	15.75	21.0
Total Volume Per Min (ml/min)	210	420	630	840

autoSAT® Pulse:

Setting 1 - 10.5 mL nominal dose
Setting 2 - 21.0 mL nominal dose
Setting 3 - 31.5 mL nominal dose
Setting 4 - 42.0 mL nominal dose
Setting 5 - 52.5 mL nominal dose

autoSAT® Pulse Volume (mL) Setting (Tolerance +/- 15%)					
Breath Rate	1	2	3	4	5
15	10.5	21.0	31.5	42.0	52.5
20	10.5	21.0	31.5	42.0	52.5
25	10.5	21.0	31.5	42.0	42.0
30	10.5	21.0	31.5	35.0	35.0
35	10.5	21.0	30.0	30.0	30.0
40	10.5	21.0	26.3	26.3	26.3

Total system output adjusts based on breath rate.

Note: Bolus volume testing is the average of 30 consecutive measurements and required to be within +/- 15% of the target bolus volume.

Continuous flow is setting is N/A

autoSAT Pulse N/A in this device

Continuous flow setting is N/A

autoSAT® Pulse:

Setting 1 - 16 mL nominal dose @ 15 bpm
Setting 2 - 32 mL nominal dose @ 15 bpm
Setting 3 - 48 mL nominal dose @ 15 bpm
Setting 4 - 64 mL nominal dose @ 15 bpm
Setting 5 - 80 mL nominal dose @ 15 bpm
Setting 6 - 96 mL nominal dose @ 15 bpm
Setting 7 - 128 mL nominal dose @ 15 bpm
Setting 8 - 160 mL nominal dose @ 15 bpm
Setting 9 - 192 mL nominal dose @ 15 bpm

autoSAT® Pulse Volume (mL) Setting (Tolerance +/-15%)									
Breath Rate	1	2	3	4	5	6	7	8	9
15	16	32	48	64	80	96	128	160	192
18	16	32	48	64	80	96	128	160	160
23	16	32	48	64	80	96	128	128	128
31	16	32	48	64	80	96	96	96	96
37	16	32	48	64	80	80	80	80	80
40	16	32	48	64	74	74	74	74	74
mL/ Min	240	576	864	1152	1440	1728	2304	2880	

Note: Bolus volume testing is the average of 30 Consecutive measurements and required to be within +/- 15% of the target bolus volume.

Continuous Flow Settings:

- 0.5 liters per minute
- 1.0 liters per minute
- 1.5 liters per minute
- 2.0 liters per minute
- 2.5 liters per minute
- 3.0 liters per minute

Oxygen Outlet Pressure	Maximum Outlet Pressure <30 PSI	<22 PSI Max 18.2 PSI (129 kPa) +/-10%	5.0 psig (34.5 kPa) Nominal (continuous flow)
Operating Conditions	Operating Temperature: 41 Fº - 104 Fº Humidity:15-95% RH noncondensing Altitude: -1250 to 10,000 Ft.	Operating Temperature: 41 Fº - 104 Fº Humidity: 0 – 95% RH noncondensing Altitude: Up to 10,000 Ft.	Operating Temperature: 32 Fº - 104 Fº Humidity: 10%-95% @ an 82.4º F dew point Altitude: 0-13,133 Ft
Dose Sensitivity	>-0.1 cm H2o (adjustable)	-0.12 cm H2o	0.135 - 0.37 cm H2o (adjustable)
Bluetooth Technology	myCAIRE App – BLE Connection to Android or iPhone. The FreeStyle Comfort Oxygen Concentrator is capable of Bluetooth functionality with the myCAIRE App.	Inogen Connect App – BLE Connection to Android or iPhone. The Inogen Rove 4 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App.	Not equipped with Bluetooth technology
Weight	• 5 lbs. (2.3 kg) w/ single battery pack • 6 lbs. (2.7 kg) w/ double battery pack	• 3.0 lbs. (1.4 kg) w/ 4-cell battery • 3.3 lbs. (1.5 kg) w/ 8-cell battery	• 14 lbs. (6.53 kg) w/ 12 cell lithium-Ion battery pack • 16 lbs. (7.26 kg) w/ 24 cell lithium-Ion battery pack
Dimensions	With Single Battery: 10.0" H. 7.3" W.3.1" D (25.4 cm. 18.5 cm. 7.9 cm) With Double Battery: 11.0" H. 7.3" W.3.1" D (27.9 cm. 18.5 cm. 7.9 cm)	With 4-Cell Battery: 7.5" H. 6" W. 2.7" D (19.1 cm. 15.2 cm. 6.9 cm) With 8-Cell Battery: 7.8" H. 6" W. 2.7" D (19.7 cm. 15.2 cm. 6.9 cm)	13.6" H X 10.6" W X 7.4" D (34.5 cm.26.9 cm.18.8 cm)
Operating Nominal Sound Level	43 dB(A) @ setting 2 (MDS-Hi) Maximum sound power of 51 dBA Maximum system sound pressure of 51 dBA Typical alarm sound pressure of 56.49 dBA (Sound pressures measured at 1 meter per ISO 3744)	39 dB(A) @ setting 2 (MDS—Hi) Maximum sound power of 59 dBA Maximum system sound pressure of 51 dBA Typical alarm sound pressure of 53 dBA (Sound pressures measured at 1 meter per ISO 3744	46 dB(A) @ 3LPM (continuous flow mode) 40 dB(A) @ setting 3 (pulse mode)
Performance and Electrical Safety and EMC	• IEC 60601-1:2012+AMD1:2020 • IEC 60601-1-2:2015+A1:2021 Ed.4.1 • IEC 60601-1-6:2020 • IEC 60601-1-8:2020 • IEC 60601-1-11:2020 • ISO 80601-2-69:2020 Ed. 2 • ISO 80601-2-67:2020 Ed. 2 • IEC 62366-1:2015	• IEC 60601-1:2012 • IEC 60601-1-2:2020 • IEC 60601-1-6:2020 • IEC 60601-1-8:2012 • IEC 60601-1-11:2015 • ISO 80601-2-69:2020 • ISO 80601-2-67:2020 • IEC 62366-1	• IEC 60601-1:1988+A1:1991+A2:1995 • IEC-60601-1-2:2001+A1:2004 • ISO 8359:1996
Biocompatibility	Externally Communicating, Tissue Permanent Duration (>30 days) ISO 18562-2:2017 - Particulate matter ISO 18562-3:2017 - Volatile organic compounds	Externally Communicating, Tissue Permanent Duration (>30 days) ISO 18562-2:2017 - Particulate matter ISO 18562-3:2017 - Volatile organic compounds	No testing to ISO 18562 1 and 2 – FDA clearance predates standard requirements.

SUBSTANTIAL EQUIVALENCE DISCUSSION

Intended Use/Indications for Use

The FreeStyle Comfort and Predicate device have similar Intended Use/Indications for use. The Subject and Predicate device provide a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. The FreeStyle Comfort and Predicate device are to be used as an oxygen supplement, may be used in the home, institution, transport modalities and are not intended for life support. FreeStyle Comfort has included this statement as part of the Intended Use/Indications for Use statement.

Technological Characteristics and Operating Principles

The Subject and Predicate device operate on Pressure Swing Adsorption (PSA) technology to produce oxygen and deliver it to patient via a standard oxygen nasal cannula. The devices deliver a bolus of oxygen upon sensing a pressure change at the start of inhalation. The oxygen concentration produced is the same with the Subject device and Predicate devices.

There are no differences which raise questions regarding the safety or effectiveness.

Non-clinical Testing

Testing included:

- ISO 80601-2-69 - Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment
- ISO 80601-2-67 - Medical Electrical Equipment - Part 2-67: Particular Requirements for Basic Safety and Essential Performance of Oxygen-Conserving Equipment.
- Pulse, volume; Pulse Time; Trigger Sensitivity; Oxygen Concentration Performance; Oxygen Sensor Accuracy; Visible/Audible Alarms
- Software verification and validation
- Electrical Safety / Electro-Magnetic Compatibility (EMC) / RFID
- Biocompatibility
- ISO 18562-2:2017 - Particulate matter
- ISO 18562-3:2017 - Volatile organic compounds
- Sound testing.

The FreeStyle Comfort and Predicate device meet safety, collateral, and performance standards required for portable oxygen concentrators verified through both internal and third-party testing to FDA recognized consensus standards.

The FreeStyle Comfort Oxygen Concentrator met all requirements.

Other Similarities

- The oxygen concentration produced by the Subject and Predicate device is the same.
- Operating environmental conditions are similar for the Subject and Predicate device.

The user interface for the Subject device is similar to the Predicate device.

The Subject and Predicate device use the same sources of power, wall outlet, battery, and DC adapter.

The Subject device can operate in both the autoSAT and fixed minute pulse dose modes. The Referenced Predicate uses the autoSAT feature to deliver a bolus of oxygen to the patient. The Predicate device uses a “fixed” minute feature to deliver a bolus of oxygen to the patient. Flow settings 1-4 are identical with both the Subject and Predicate devices.

The Subject and Predicate device are intended for adult use in homes, institutions, and transport modalities.

The remarks column in the Substantially Equivalence Device Comparison Table notes the similarities, substantial equivalence, and differences to the line items listed in the table

Discussion of Differences

The major differences between the Subject device and the Predicate devices are:

- The device dimensions and weight - The Predicate device is smaller and lighter than the Subject device.
- Battery pack cells - The Predicate uses either a 4-cell or 8-cell battery whereas the Subject device uses either an 8-cell or 16-cell battery pack.
- Flow settings – The Predicate device offers four (4) fixed oxygen flow settings. The Subject device offers five (5) fixed flow settings plus the autoSAT flow functions similar to the Referenced Predicate, eQuinox. The cleared Referenced Predicate device, eQuinox, has nine settings and for breath rates shown, at least 4 of the setting are higher than setting 5 (max) of the Subject Device.

The above differences noted between the Subject and Predicate devices do not raise any additional concerns regarding safety or effectiveness

Substantial Equivalence Conclusion

The Subject and Predicate device have been found to be substantially equivalent. The FreeStyle Comfort and Predicate device have similar fundamental technology, operating systems, components/materials, operating principles and the same delivered concentrated oxygen, 90%+5.5% / -3%. The indications for use are the same between the FreeStyle® Comfort® and the Predicate device.

The above comparison demonstrates that the FreeStyle® Comfort® has no significant technological differences from the Predicate device that would raise any additional concerns regarding product safety and effectiveness.