October 17, 2022

Effortless Oxygen. LLC
% Paul Dryden
Consultant
Effortless Oxygen. LLC c/o Promedic, LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K221014
Trade/Device Name: Effortless Oxygen Conserver System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NFB
Dated: September 16, 2022
Received: September 16, 2022

Dear Paul Dryden:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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

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

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

Sincerely,

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221014

Device Name
Effortless Oxygen Conserver Systems

Indications for Use *(Describe)*

The Effortless Oxygen Conserver Systems are intended to deliver medical-grade oxygen for patients that require supplemental oxygen from oxygen gas sources. Pulsing oxygen allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The Effortless MOBILE may be used in hospital, healthcare facilities, or home care environments. The Effortless PRO is only intended for hospital and healthcare facilities under professional use.

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

Date Prepared: 17-Oct-22

Sponsor:
Effortless Oxygen, LLC
251 E Sierra Dr.
Phoenix, AZ 85012

Official Contact: Samir Ahmad

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: Effortless Oxygen Conserver Systems
- Effortless Pro
- Effortless Mobile

Common/Usual Name: Oxygen Conserver
Classification CFR: 21 CFR 868.5905
Classification Code: NFB
Classification Name: Conserver, Oxygen

Predicate Device: Inspired Model 350G Gas Conserver
510(k): K090421
Common/Usual Name: Oxygen Conserver
Classification CFR: 21 CFR 868.5905
Classification Code: NFB
Classification Name: Conserver, Oxygen

Device Description:
The Effortless Oxygen Conserver Systems (EOCS) is a microprocessor-controlled device, which contains an oxygen pressure regulator and oxygen conserver. Depending upon the model they have been designed for use in ambulatory, home and medical facility settings to supply medical-grade oxygen therapy to patients. The built in oxygen regulator reduces oxygen pressures from an oxygen cylinder or from hospital wall supplies.

There are two configurations: The Effortless Pro which connects to hospital wall oxygen and the Effortless Mobile which connects to tanks.

Users:
Mobile: The User of the Mobile is a patient or caregiver in any setting where tank of oxygen is available, including home and clinical settings. e.g., acute hospital facility, nursing home, or long-term care facility.

Pro Model: The Pro includes additional features for professional use only. The User of the Pro is a licensed medical Healthcare Professional (HCP) (i.e. physician, nurse, respiratory therapist or delegated medical professional) in a clinical setting e.g., acute hospital facility, nursing home, or long-term care facility. The Pro is not intended for use in a home-based setting.

Patient Interface:
When connected to a standard oxygen nasal cannula, the device senses the inspiration of the patient using a flow sensor and delivers a precise bolus of oxygen to the patient. The device allows for settings of pulse flow oxygen therapy from 1–6.

The Effortless Pro and Mobile models are multi-patient multi-use, the cannula is single patient use.

The devices can be externally powered from an IEC 60601-1 power supply or powered from an integral rechargeable lithium-ion battery.

The devices use identical control modules, with the primary difference being in the display of Trigger rate (in the Pro) and mechanical connection to the oxygen source and pressure regulation

Indications for Use:
The Effortless Oxygen Conserver Systems are intended to deliver medical-grade oxygen for patients that require supplemental oxygen from oxygen gas sources. Pulsing oxygen allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The Effortless MOBILE may be used in hospital, healthcare facilities, or home care environments. The Effortless PRO is only intended for hospital and healthcare facilities under professional use.

Patient Population:
Patients that require supplemental oxygen.

Environments of use:
Hospital, healthcare facilities, or home care (Mobile model only) environments.

We present the proposed device vs. the predicate in table below.

Table of Comparison and Differences

The table below outlines the features of the Effortless Pro and Mobile and compares it to the predicate device to establish substantial equivalence.

	Proposed **Effortless Pro and Mobile**	**Predicate** **Inspired Technologies** **Model 350G – K090421**	**Comments**
Classification	NFB - conserver, oxygen Regulation Description - Noncontinuous ventilator (IPPB) CFR 868.5905	NFB - conserver, oxygen Regulation Description - Noncontinuous ventilator (IPPB) CFR 868.5905	Similar
Indications for Use	The Effortless Oxygen Conserver System is intended to deliver medical-grade oxygen for patients that require supplemental oxygen from oxygen gas sources. Pulsing oxygen allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The Effortless MOBILE may be used in hospital, healthcare facilities, or home care environments. The Effortless PRO is only intended for hospital and healthcare facilities under professional use.	The Inspired Technologies 350G Gas Conserver is intended as a delivery medial-grade device for oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The 350G Gas Conserver is intended to be used in the hospital, healthcare facilities, or home care environments.	Similar
Environments of use	Hospital, healthcare facilities, or home care environments depending upon the model	Hospital, healthcare facilities, or home care environments	Similar
Population	Patients that require supplemental oxygen	Patients that require supplemental oxygen	Similar
Prescriptive	Yes	Yes	Similar
Technology	Delivers oxygen in a pulsed dose to the patient by sensing inhalation. Delivers oxygen via nasal cannula to both nostrils	Delivers oxygen in a pulsed dose to the patient by sensing inhalation. Delivers oxygen via nasal cannula to both nostrils	Similar technology
Software driven	Yes	Yes	Similar
Dosing algorithm and number of settings	1, 2, 3, 4, 5, 6 (Liters per Minute Equivalent at 16 ml per setting +/- 15%)	16 ml/lpm (accuracy not provided) Setting (lpm) 1, 1.5, 2, 2.5, 3, 4, 5, 6 Sport modes	Similar dosing algorithm Similar range of settings

	Proposed Effortless Pro and Mobile	Predicate Inspired Technologies Model 350G – K090421	Comments
Alarms	Trigger rate – Low if no trigger < 15 sec, High if trigger rate > 30 / min Loss of Oxygen Pressure Low Battery	Visual battery low alert No audible alarms	Similar
Back-up mode	Pro Model - 1, 2, 3, 4, 5, 7, 9, 11, 13, 15 (Liters per Minute, selectable) Mobile Model – 2 Lpm continuous flow only	Continuous flow - 2 Lpm	Both have a means for back-up mode
	Back-up Mode is a user activated mode which provides a continuous flow of oxygen controlled by a purely mechanical valve that does not require electrical power and operates independently of the electronic system. It is typically used on low or no battery situations.	Back-up Mode is a user activated mode which provides a continuous flow of oxygen controlled by a purely mechanical valve that does not require electrical power and operates independently of the electronic system.	Similar
Power source	Rechargeable Li battery	4 – "AA"	Similar
Status Indicators	Alarm status Pulse setting Low battery Low pressure of gas source Audible beeps Breath rate alarm	Device "on" patient setting-valve activation Battery status No audible alarms	Different, the subject device has more indicators which would be considered to be a benefit and not raise different concerns or risks
Trigger sensing	<0.01 cmH_2O	+0.03 to -0.2 cmH_2O	Similar subject device is more sensitive
Trigger range	Up to 40 trigger event / min	Up to 35 trigger event / min	Similar
Operating conditions	10°C to 40°C RH 10-90% Altitude: -304 .8 (1.04 atmosphere) to 3,048 meters (0.69 atmosphere) (-1,000 to 10,000 feet)	Not specified	Subject device meets typical operating ranges

	Proposed Effortless Pro and Mobile	Predicate Inspired Technologies Model 350G – K090421	Comments
Size	Pro Height: 90mm (3.5”), Width:100mm (4”), Depth: 150mm (6”) Weight – 0.7 Kilogram (1.5 Pounds) Mobile: Height: 90mm (3.5”), Width:100mm (4”), Depth: 150mm (6”) Weight – 0.7 Kilogram (1.5 Pounds)	Not specified	Similar to be attached to a cylinder or t the wall gas outlet
Accessories	Nasal cannula, single patient, multi-use	Nasal cannula, single patient, multi-use	Similar, user supplied for subject device
Standards	IEC 60601-1: 2005 +A1:2012 IEC 60601-1-2: 2014 IEC 60601-1-11:2015 ISO 80601-2-67: 2012	IEC 60601-1	Subject device meets current standards and revisions
Biocompatibility	Externally communicating, Tissue Duration – permanent ISO 18562-2 – PM ISO 18562-3 – VOC	Externally communicating, Tissue And Surface contact, Skin and Mucosa Duration – permanent	Similar

Substantial Equivalence Discussion

The table above compares the key features of the proposed device with the predicate. The comparison demonstrates that the proposed devices can be found to be substantially equivalent.

The EOCS is viewed as substantially equivalent to the predicate device because:

Indications –

- The EOCS is an oxygen conserving device.

Discussion – The indications for use are similar to the predicate K090421. The subject device is also indicated for wall oxygen, this has no bearing on the use or effect of the device.

Environment of Use –

- The subject and predicate devices have the same environments of use.

Discussion – The environments of use and personnel are similar to the predicate.

Technology –

- The technological principles of delivers oxygen in a pulsed dose to the patient by sensing inhalation. Oxygen is delivered via nasal cannula to the nostrils.
- Trigger Rate
    - When connected to a standard nasal cannula attached to a patient, the device senses the inspiration of the patient using a flow sensor. When the flow sensor detects a drop in pressure, which occurs during the start of inspiration, it triggers the device to deliver the pre-set / prescribed bolus of oxygen to the patient.
    - The Pro device displays a moving average of the last 3 triggers converted to triggers per minute. The Mobile model is measuring trigger rate but is not displaying a numerical value.
    - A trigger is defined as the system detecting inhalation and triggering a pulse of oxygen. The trigger Rate (TR) is calculated as the time between triggers converted into triggers per minute and displayed as a moving average:

Discussion – The devices are the same.

Non-clinical Testing Summary -

Biocompatibility of Materials

- The materials in patient contact have been tested to per ISO 18562-2 and 18562-3.

Discussion – The materials met the requirements per the applicable standards.

Electrical, EMC, EMI testing

- We have evaluated the proposed device per ANSI/AAMI/ES 60601-1, IEC 60601-1-2 and ISO 80601-2-67 the device performed as intended and met the requirements.

Discussion – The proposed device met the requirements of the standards and is considered safe.

Bench testing –

- Bench testing was performed to verify the performance to specifications of the proposed device. Testing include ISO 80601-2-67:
    - Testing includes:
    - Trigger Delay
    - Trigger Sensitivity
    - Trigger Rate
    - Performance at Different Gas Source Pressures
    - Delivered Pressures at Nostrils
    - Continuous Flow Rate
    - Pulse Volume
    - Human Factors

Discussion – The proposed devices were tested to assure that they meet performance specifications. Upon completion of the tests, it was found to meet its performance requirements.

Discussion of Differences

There are no differences which raise different concerns or risk of safety or effectiveness between the proposed device and the predicate device.

The performance testing has demonstrated that the subject device met the applicable standard performance requirements. The above table plus the risk analysis do not identify any different risks compared to the predicate.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.