July 24, 2020

3B Medical Inc.
Yasser Estafanous
QA/RA Director
203 Avenue A NW, Suite 300
Winter Haven, Florida 33881

Re: K200496
Trade/Device Name: Aer X
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: June 22, 2020
Received: June 24, 2020

Dear Yasser Estafanous:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200496

Device Name
Aer X

Indications for Use *(Describe)*
The Aer X oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Aer X may be used in home, institution, vehicle and various mobile environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter:	3B Medical Inc. 203 Avenue A NW Suite 300 Winter Haven, FL 33881
Contact Person:	Yasser Estafanous Director of QA/RA Telephone: 863-226-6285 Fax: 863-226-6284 Email: yestafanous@3bproducts.com
Date Prepared:	July 17, 2020
Trade Name:	Aer X Portable Oxygen Concentrator
Common Name:	Oxygen Concentrator
Classification:	Class II
Product Code:	CAW, 21 CFR 868.5440
Predicate Device(s):	The subject device is equivalent to the following devices: • VBOX Trooper (K121260)
Device Description:	The Aer X oxygen concentrator utilies a molecular sieve and a differential pressure swing adsorption methodology to separate the gases in ambient air. The device takes the room air and concentrates the oxygen portion to produce a pulseof oxygen between 87-94% in purity. When the patient inhales, the device senses the pressure change and is triggered to release the oxygen pulse. In between breaths, the device regenerates an oxygen pulse and waits for the next inhalation breath before dispensing it
Intended Use:	The Aer X oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Aer X may be used in home, institution, vehicle and various mobile environments.

Comparison to the Predicate Device

Table 1. Comparison to Predicate Device

	Aer X Oxygen Concentrator (Subject Device)	VBOX Trooper Oxygen Concentrator (Predicate Device)
510(k) Number Decision Date	K200496	K121260
Manufacturer	3B Medical Inc.	VBOX
Classification	Class II	Class II
Product Code	CAW	CAW
Regulation	21 CFR 868.5440	21 CFR 868.5440
Indications for Use	The Aer X oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Aer X may be used in home, institution, vehicle and various mobile environments.	The Trooper oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Trooper may be used in home, institution, vehicle and various mobile environments.
Prescription Required	Yes	Yes
Patient Interface	Same Standard nasal Cannula	Standard nasal cannula
Dimensions (LxWxH)	7.125”x8.25”x2.75’’inches	6 x 2.5 x 6.25 inches
Weight	4.2 lbs (includes battery)	3.2 lbs (includes battery)
Materials		
Sieve Bed	Synthetic zeolite	Synthetic zeolite
Sieve bed cartridge	Adsorbent Cartiradges	Adsorbent Cartiradges
Battery	Li-Ion	Li-Ion
Performance Specifications		
Method of oxygen concentration	Molecular sieve (mechanical)	Molecular sieve (mechanical)
Process by which Oxygen is released	Differential pressure swing adsorption	Differential pressure swing adsorption
Flow Rate	5 settings: 1 to 5 (flow rates equivalent to 1 LPM to 5 LPM)	5 settings: 1 to 5 (flow rates equivalent to 1 LPM to 5 LPM)

Table 1. Comparison to Predicate Device

Duration of flow	Pulsed	Pulsed
Trigger Sensitivity	0.13 cm water (12.7 Pa)	0.13 cm water (12.7 Pa)
Oxygen concentration (% O_2)	87-94% at all settings	87-94% at all settings
Software/ Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
Rechargeable Battery	Yes	Yes
Power Options	Battery, AC	Battery, AC
Technological charactartristics Summary		
Produce of high purity O2	Differential pressue vacuum swing adsorption method	Differential pressue vacuum swing adsorption method
Flow	Pulsed	Pulsed
Cycles to produce concentrated O2	1) Dispense, 2) Evacuate and 3) Pressurize	1) Dispense, 2) Evacuate and 3) Pressurize
Material inside adsorbent cartridge	Synthetic Zeolit	Synthetic Zeolit

A summary of technological Characteristics of the new device in comparison to those of the predicate device.

New Changes to the Aer X as compared to the VBOX TROOPER

1.Exterior Shape- The exterior housing shape was required to change due to the Battery change below and the Keypad/ Display change below. The material for the exterior housing is PolyCarb/ ABS with the same fire-retardant rating as was the original device.

2. Battery Location changed from an exterior position with cord and plug to an integrated separate battery chamber with protected style of plug that does not require user to maneuver the plug into position.

3. LCD display with Keypad was updated to more tactile buttons and a color LCD in place of a segmented display.

4. Magnetic Cannula is a new feature to create a “breakaway” cannula that will protect the user and device in the event of the cannula tubing being “caught” on an object. The shape of the cannula plug is shaped to fit the industry standard cannula profile. The cannula plug was also changed to anodized aluminum to keep with industry standards for that component.

5. new design for the Carry Bag needed to change to fit the new exterior shape, also to have a flap that covers the display keypad.

Technology not changed:

- **Battery Power:** 18650 Li Ion cells in a battery Pack that is user changeable and user chargeable, as before.
- **O2 Production**-Separation uses the same Vacuum Pressure swing, purge and repressurizing algorithm employing LILSX adsorbent with high nitrogen capacity. Valving and timing to provide purge and blow down technology is also employed, as before.
- **O2 Product Flow Rate:** Oxygen is delivered by the Aer X device via a nasal cannula the same standard 2 prong cannula, the Oxygen is delivered in pulse mode a bolus of oxygen at the beginning of each inhalation. The purity of the oxygen is 90% +4% -3% (87-94%) which is also an industry standard for portable oxygen concentrators. The oxygen flow rate is in 5 settings 1 to 5 to be equivalent to 1 LPM to 5 LPM.

Functional and Safety Testing:

To verify that the modified device design met it's functional and performance requirements, representative samples of the device underwent biocompatibility, electrical, and mechanical testing in accordance with applicable industry standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, and ISO 80601-2-69.

Non-clinical testing(Bench testing)

Bench testing was performed to provide assurance that the proposed device confirm to the requirements for its intended use. This include the following

- Output gas composition (e.g. VOCs, particulate matter, ozone/carbon monoxide/carbon dioxide content).
- User display and LED functions
- Oxygen flow rate and concentration
- Electromagnetic compatibility and electrical safety
- Functional performance
- Output gas temperature.

Summary of results :

As outlined above, the principles of operation, technology, materials and indications for use of the subject device are equivalent to those of the predicate device. The differences in size, weight, LCD & Keypad, exterior housing, carry bag, and the cannula port do not introduce any different questions of safety and effectiveness over the predicate device. The information demonstrates that the subject device is substantially equivalent to the predicate device.

Conclusion:

3B Medical Inc. considers the Aer X to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.