December 8, 2022

Longfian Scitech Co., Ltd.
% Jun Peng
Principal Consultant
P&L Scientific, Inc.
1430 S. Dixie Hwy Suite 105
Coral Gables, Florida 33146

Re: K213210
Trade/Device Name: Oxygen Concentrator, Model JAY-5AW
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 3, 2022
Received: November 7, 2022

Dear Jun Peng:

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 -S

James J. Lee, Ph.D.
Division 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)*
K213210

Device Name
Oxygen Concentrator, Model JAY-5AW

Indications for Use *(Describe)*
The Longfian Oxygen Concentrator, Model JAY-5AW is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model JAY-5AW, can be used at home or healthcare environments. The Longfian Oxygen Concentrator, Model JAY-5AW, does not nor is it intended to sustain or support life. The device is intended for use in adults.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based:

K213210

1. Submitter Information:

- **Sponsor/510(K) Owner:**
  LONGFIAN SCITECH CO., LTD.
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  Baoding 071051, China

  Contact: Mr. Shi Lei
  Technical Manager
  Phone: +86-312-5909505

  Date: October 28, 2022

- **Contact Name:**
  Mr. Jun Peng
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  1430 S. Dixie Hwy STE 105, Coral Gables, FL 33146
  Phone: (305) 345 6018
  Fax: (305) 397 0289
  Email: jpeng@plscientificinc.com

2. Device Name

Trade Name: Oxygen Concentrator, Model JAY-5AW
Common Name: Oxygen concentrator;
Classification Name: Oxygen concentrator, portable;

3. Classification :

Classification: 21 CFR 868.5440; Class II
Product Code: CAW;

4. Predicate Devices:

Oxygen Concentrator (Model: JAY-5)	K131968, Cleared September 5, 2014	LONGFIAN SCITECH CO., LTD.

5. Description of Device

The Longfian Oxygen Concentrator, Model JAY-5AW adopts pressure swing adsorption principle, which can separate oxygen, nitrogen and other gas from the air, at constant temperature. As soon as power is connected, the air is taken in and compressed by oilless

air compressor through filtering, then the compressed air goes through the cooler and it is cooled. After that, the air is taken into absorption tower by control valve and the oxygen can be separated in the absorption tower. At the same time, the high purity oxygen is collected into the oxygen tank, and it goes through the flow meter and humidifier, finally the oxygen that meets medical standards can be supplied. Oxygen is generated by pure physical method.

The device is capable of providing oxygen flow up to 5 LPM. The concentration of supplied oxygen is from 90%-96%. The weight of Jay-5AW is around 16kg (~35lbs). There is no influence on indoor oxygen percent during the generator operating.

The biocompatibility contact classification of the device is as permanent contact externally communicating with dry and humified gas pathway.

The life-time/use life of the oxygen concentrator is set at 5 years or 20,000 hours after the product is sold, whichever comes first.

The reusable components:

- Intake air filter (two pieces, part number:GL-01)
- Secondary filter (one piece, part number:GL-02)
- nasal oxygen tube and
- humidifier.

JAY-5AW medical oxygen concentrator contains the following items:

- One (1) JAY-5AW Oxygen Concentrator Unit
- One (1) AC Power Supply
- One (1) Nasal Oxygen Tube
- One (1) Firesafe Cannula Valve
- One (1) Humidifier
- One (1) Operation Manual

6. Intended Use

The Longfian Oxygen Concentrator, Model JAY-5AW, is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model JAY-5AW, can be used at home or healthcare environments. The Longfian Oxygen Concentrator, Model JAY-5AW, does not nor is it intended to sustain or support life. The device is intended for use in adults.

7. Summary of Comparison in to Technological Characteristics Predicate Device

Name	Predicate device	Subject device
K number	K131968	K213210

Device Trade Name	JAY-5 Medical Molecular Sieve Oxygen Concentrator	The Longfian Oxygen Concentrator, Model JAY-5AW
Common Name	Oxygen concentrator	Oxygen concentrator
Classification Name	Oxygen concentrator, Portable	Oxygen concentrator, Portable
Indications for use	The Longfian Oxygen Concentrator, Model Jay-5 is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model Jay-5 can be used in a home, institution, vehicle, and various mobile environments. The Longfian Oxygen Concentrator, Model Jay-5 does not nor is it intended to sustain or support life.	The Longfian Oxygen Concentrator, Model JAY-5AW, is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Longfian Oxygen Concentrator, Model JAY-5AW, can be used at home or an institution. The Longfian Oxygen Concentrator, Model JAY-5AW, does not nor is it intended to sustain or support life. The device is intended for use in adults.
Classification	21 CFR 868.5440	21 CFR 868.5440
Feature		
Power supply	AC 220±22V， 50±1Hz	AC 230±23V, 50±1Hz
Input power	500W	460W
Oxygen concentration	93%±3%	93%±3%
Oxygen flow	0~5L/min	0~5L/min
Outlet pressure	40~70kPa	40~70kPa
Noise	≤53dB(A)	≤53dB(A)
Fuse	T6.3AL/250V	F5AL/250V
Operating system	Pressure Swing Adsorption	Pressure Swing Adsorption
Electrical classification	Class II Type B	Class II Type B
Dimensions	365×375×600mm (14.37"×14.76"×23.62")	280×3485×510mm (14.37"×14.76"×23.62")
Net weight	26Kg	16Kg
Alarm	Low & high pressure	Low & high pressure; Power failure
LCD display	Accumulating timing; present timing; timing	Accumulating timing; present timing; timing
Accessories	Nasal oxygen tube Humidifier	Nasal oxygen tube Humidifier
Materials		
Sieve Bed	Synthetic Zeolite	Synthetic Zeolite
Nasal Oxygen Tube	PVC	PVC
Principles of operation		
Operating system	Time cycle/ Pressure Swing Adsorption	Time cycle/ Pressure Swing Adsorption

Electronic safety	Electrical Safety per IEC-60601	Electrical Safety per IEC-60601
Software/Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
Operating , transportation and storage environment		
Operating conditions	Ambient temperature :10~40℃ Relative humidity:30%~85% Atmospheric pressure:700 1060hPa	Ambient temperature :10~40℃ Relative humidity:30%~85% Atmospheric pressure:700 1060hPa
Transportation and storage Conditions	Ambient temperature :-20~45℃ Relative humidity: ≤95% Atmospheric pressure 500-1060hPa	Ambient temperature :-40~45℃ Relative humidity: ≤95% Atmospheric pressure 700-1060hPa

The Longfian Oxygen Concentrator, Model JAY-5AW is similar to the predicate devices:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics
- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

The differences are:

- JAY-5AW has different enclosure shape comparing to JAY-5;
- The two models use different power of compressor, but compressor principle is the same, the electronical safety and performance testing has validate the safety and effectiveness of JAY-5AW;
- The differences in dimensions and weight do not raise any issues in safety and effectiveness.

8. Assessment of Non-Clinical Testing:

Non-clinical testing of the Longfian Oxygen Concentrator, Model JAY-5AW has been performed against requirements for performance, physical attributes, environmental conditions, materials and safety, and to provide objective evidence that the device's intended use is met.

9. Test Summary:

The device has been evaluated the safety and performance by lab bench testing as following:

Biocompatibility testing:

The biocompatibility evaluation for the Longfian Oxygen Concentrator, Model JAY-5AW was conducted in accordance with the ISO18562-1, ISO 18562-2, ISO18562-3, ISO10993-5, ISO10993-10, ISO10993-17.

Electrical safety and electromagnetic compatibility (EMC):
Electrical safety and EMC testing were conducted on the Longfian Oxygen Concentrator, Model JAY-5AW. The system complies with the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC60601-1-11, and ISO 80601-2-69 standards for electrical safety and the IEC60601-1-2 standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." **Level of Concern:** The software for this device was considered as a moderate level of concern, because the subject device is a supplement to a patient's normal oxygen intake. If a failure of operation or latent design flaw could directly result in minor injury to the patient or operator. The device is not intended to be life supporting or life sustaining.

Performance Bench Testing
The basic safety and essential performance Test were evaluated based on ISO 80601-2-69. And Oxygen concentration and maximum flow performance testing was also conducted to verify that oxygen production capacity of the oxygen generator can meet the design requirements after working continuously at the maximum output for 8 hours

10. Conclusion

The subject device and the predicate device have the same intended use. The technological differences do not raise different questions of safety and effectiveness