OXYGEN CONCENTRATOR

Features

- Low maintenance, easy to care for
- USA imported humidifier 6PSI pressure release
- Higher outlet pressure to ensure people flow delivery
- Innovative cooling technology to improve reliability and life of the unit
- Big LCD display to show the switch and accumulated working time, operating pressure

Technical Parameters

Model	JAY – 5B (Longfian Scitech Ltd)
Flow rate	0–5L/min
Oxygen purity	93±3%
Outlet pressure	0.04–0.07Mpa
Noise level	≤43db
Power Supply	AC230V, 50Hz; AC220V/110V (±10%), 50/60Hz (±1Hz)
Power consumption	≤540W
LCD display	Switch times, operating pressure, present working time, accumulated working time, preset time from 10mins to 40hours
Alarm	Power failure alarm
Size	360x300x600mm
Net weight	22kgs
Optional configuration	1. Nebulizer (Atomization): >10L/min 2. SPO2(Pulse oximeter) 3. Low purity alarm: when oxygen purity is above 82% ,it will give blue light, when the purity is below 82%(82% not included),it will give red light 4. High temperature alarm(Inside system temp above 50℃

Justcare

HOMECARE OXYGEN CONCENTRATOR

MODEL：JAY-5BW

Higher outlet pressure to ensure proper flow delivery

Low maintenance, easy to care for

Optional pulse oximeter

Specification

Flow Rate	0-5LPM
Purity	93% (±3%)
Outlet Pressure	0.04-0.07MPA(6-10PSI)
Sound Level	⩽43db
Power Consumption	(⩽540w
LCD Display	Switch times, operating pressure, present working time, accumulated working time, presetting time from 10mins to 40hours
Alarm	Power Failure alarm, High&low pressure alarm
Net Weight	24Kgs
Size	360×300×600mm

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland®

Registration No.: DD 60136153 0001

Report No.: 16802952 009

Manufacturer:
LONGFIAN SCITECH CO., LTD.
2F&3F, East Section, Building 12
Power valley pioneer park
No. 369 Huiyang street
Baoding
071051 Hebei
China

Products:
Medical Oxygen Concentrators

Replaces Approval, Registration No.: DD 60108301 0001

Expiry Date: 2024-03-18

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-03-19

Date: 2019-03-18

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

LONGFIAN SCITECH CO., LTD.
2F&3F, East Section, Building 12
Power valley pioneer park
No. 369 Huiyang street
Baoding
071051 Hebei
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Oxygen Concentrators

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-04-18
Certificate Registration No.:	SX 60136154 0001
An audit was performed. Report No.:	16802952 007
This Certificate is valid until:	2022-03-18

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-04-18

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
III
Zertifizierungsstelle

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2014

Longfian Scitech Co., Ltd.
c/o Mr. Jun Peng
P&L Scientific, Inc.
6840 SW 45th LN Unit 5
Miami, FL 33155

Re: K131968
Trade/Device Name: OXY.LIFE Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Oxygen concentrator, portable
Regulatory Class: Class II
Product Code: CAW
Dated: August 1, 2014
Received: August 7, 2014

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LONGFIAN SCITECH CO., LTD
2F&3F, East Section, Building 12, Power valley pioneer park,
NO.369 Huiyang street , 071051,Baoding, Hebei Province,China
Tel: 0086-312-5909505; 0086-312-5954096

AUTHORIZATION LETTER

WHEREAS
We, **LONGFIAN SCITECH CO., LTD** are reputable manufacturers of oxygen concentrator, having factories at:2F&3F, East Section, Building 12, Power Valley Pioneer Park, NO.369 Huiyang street 071051, Baoding, Hebei Province,China

THEREFORE, we do Authorize our Valued Customer, SURYA SURGICAL INDUSTRIES, CHENNAI, INDIA to SELL our products to RAINSTONE INTERNATIONAL DMCC, DUBAI, UAE, and they in full responsibility to market and service, subsequently negotiate and sign the contracts on our behalf.

We also Authorize RAINSTONE INTERNATIONAL DMCC to resell, reship to any other countries as a company policy to support the Pandemic and People in need for our products.

This authorization is valid till Apr.22, 2023 from the date of issuance. If either party wants to cancel the agency agreement, it must be formally notified by email at least one month in advance.

Signed: 

In the capacity of: General Manager

Print Name: **Shi Baozhu**

Duly authorized to sign and on behalf of: LONGFIAN SCITECH CO.,LTD

Dated on: Aug 1st ,2021