July 20, 2020

Guangzhou Life Light Electronic Technology Co., Ltd.
℅ Iris Fung
Project Manager
SGS-CSTC Standards Technical Services Co., Ltd.
108 Kezhu Road
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Guangzhou, 510060 Cn

Re: K191875
Trade/Device Name: Owgels Oxygen Concentrator, Model: OZ-5-02TW0
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: March 15, 2020
Received: April 7, 2020

Dear Iris Fung:

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)*
K191875

Device Name
Owgels Oxygen Concentrator, Model : OZ-5-02TW0

Indications for Use *(Describe)*
The Owgels Oxygen Concentrator 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 Owgels Oxygen Concentrator can be used in a home, institution environments. The Owgels Oxygen Concentrator 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.

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

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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: 2020-07-06

2. Submitter's Information

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3. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Oxygen Concentrator

Trade Name: Owgels Oxygen Concentrator, Model : OZ-5-02TW0

Classification Name: Generator, Oxygen, Portable

Review Panel: Anesthesiology

Product Code: CAW

Regulation Number: 868.5440

Regulation Class: 2

4. Predicate Device Information

Sponsor	LONGFIAN SCITECH CO., LTD.
Device Name	OXY.LIFE Oxygen Concentrator
510(k) Number	K131968
Product Code	CAW
Regulation Number	868.5440
Regulation Class	2

5. **Device Description**

Owgels Oxygen Concentrator, Model : OZ-5-02TW0 adopts pressure swing adsorption principle, which can separate oxygen, nitrogen and other gas from the air, at constant temperature. The concentrator can generate oxygen with steady oxygen flowing out and reliable, adjustable flow. The device is capable of providing oxygen flow up to 5 LPM. The concentration of supplied oxygen is from 90%-96%. The weight of Owgels Oxygen Concentrator, Model : OZ-5-02TW0 is around 19kg.

6. Intended Use / Indications for Use

Intended Use

The Owgels Oxygen Concentrator 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 Owgels Oxygen Concentrator can be used in a home, institution environments. The Owgels Oxygen Concentrator does not nor is it intended to sustain or support life. The device is intended for use in adults.

Indications for use

The Owgels Oxygen Concentrator 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 Owgels Oxygen Concentrator can be used in a home, institution environments. The Owgels Oxygen Concentrator does not nor is it intended to sustain or support life. The device is intended for use in adults.

7. Test Summary

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

Biocompatibility testing

The biocompatibility evaluation for the Owgels Oxygen Concentrator, Model : OZ-5-02TW0 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 Owgels Oxygen Concentrator, Model : OZ-5-02TW0 . 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 minor level of concern,because the subject device is a supplement to a patient's normal oxygen intake. A software failure will not result in injury to a patient or user. The device is not intended to be lifesupporting or life sustaining.

Performance Bench Testing

The basic safety and essential performance Test was 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

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Owgels Oxygen Concentrator, Model : OZ-5-02TW0 is substantially equivalent to the predicate devices quoted above.

Elements of Comparison	**Subject Device**	**Predicate Device(Primary)**	**Remark**
Device Name and Model	Owgels Oxygen Concentrator, Model : OZ-5-02TW0	JAY-5 Medical Molecular Sieve Oxygen Concentrator	--
510 (K) Number	Applying	K131968	--
Product Code	CAW	CAW	SE
Regulation Number	21 CFR868.5440	21 CFR868.5440	SE
Indications for use	The Owgels Oxygen Concentrator 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 Owgels Oxygen Concentrator can be used in a home, institution environments. The Owgels Oxygen Concentrator does not nor is it intended to sustain or support life.	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	SE, Note 1

		The device is intended for use in adults.	Jay-5 does not nor is it intended to sustain or support life.	
Principles of operation		Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve	SE
Operating system		Time cycle/ Pressure Swing Adsorption	Time cycle/ Pressure Swing Adsorption	SE
Electronic safety		Electrical Safety per IEC-60601	Electrical Safety per IEC-60601	SE
Software/Hardware		Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	SE
Feature				
Oxygen Concentration		93%±3%	93%±3%	SE
Flow Specifications		0 LPM-5 LPM	0 LPM-5 LPM	SE
Acoustic Noise		< 55 dB(A)	≤53dB(A)	SE Note 2
Alarms	Low oxygen purity	Yes	Yes	SE
	Low Pressure	Yes	Yes	SE
	power outage	Yes	Yes	SE
Power requirements		120V /60 Hz	AC 230±23V, 50±1Hz	SE, Note 3
Dimensions		340 x 300 x 650 mm （13.4 inches×11.8 inches×25.6 inches）	365×375×600mm (14.37"×14.76"×23.62")	SE Note 3
Weight		19 kg	26Kg	SE
Materials				
Sieve Bed		Synthetic Zeolite	Synthetic Zeolite	SE

Note 1：

The Indications for use of the Subject Device and Predicate Device is slightly different on its use environment, but both are prescribed by a doctor with the ultimate goal of providing patients with adequate oxygen. Both devices are not life supporting or life sustaining. Therefore, the differences in the indications for use of the subject and predicate devices do not impact safety and effectiveness.

Note 2:

The subject device and the predicate device have differences in Acoustic Noise. However, the proposed device meets the requirements of the standard ISO80601-2-69 and IEC60601-1-8. Hence, there are no different questions of safety and effectiveness questions pertaining to Performance of the subject device.

Note 3：

Although the Dimensions and Power supply specifications is different from the predicate device, but both the predicate device and the proposed device has passed the IEC60601-1 test. Hence, there are no different questions of safety and effectiveness questions pertaining to Electrical Safety.

Finial Conclusion:

The subject device Owgels Oxygen Concentrator, Model：OZ-5-02TW0 is Substantial Equivalence to the predicate device.