Contec Medical System Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-med Technology Service Co., Ltd.
Rm.912, Building #15, Xiyuehui, No.5, YiHe North Rd.,
FangShan District,
Beijing, China, 102401

Re: K180837
Trade/Device Name: Contec™ Oxygen Concentrator OC3D
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: December 11, 2018
Received: December 14, 2018

Dear Ray Wang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 D. Courtney -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K180837

Device Name
CONTEC™ Oxygen Concentrator Model OC3D

Indications for Use *(Describe)*

CONTEC™ Oxygen Concentrator, OC3D, is intended to provide supplemental oxygen in a home, institutional environment. The device is only used for adult and prescription use only.

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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Tab #8 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K180837

1. Date of Preparation: 12/08/2018

2. Sponsor Identification

Contec Medical System Co., Ltd.
No.112 Qinhuang West Street, Economic & Technical Development Zone,
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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Predicate Device(s)

Predicate Device:
510(k) Number: K162433
Product Name: GCE Zen-O™ Portable Oxygen Concentrator
Model Name:RS-00500
Manufacturer:
Oxus Inc.

5. Identification of Proposed Device

Trade Name: CONTEC^{TM} Oxygen Concentrator Model OC3D
Common Name: Generator, Oxygen, Portable
Model(s): OC3D

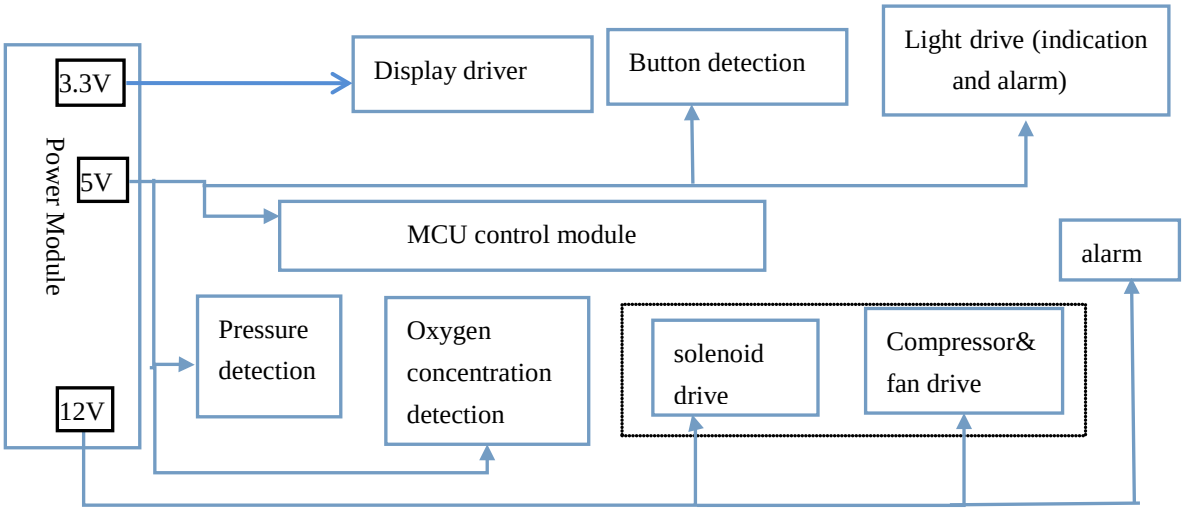
Regulatory Information
Classification Name: Portable oxygen generator
Classification: II
Product Code: CAW
Regulation Number: CFR 868.5440
Review Panel: Anesthesiology

Device Description

The Oxygen Concentrator is a small and portable oxygen concentrator. It consisted of air compressor, adsorption tower of molecular sieve, oxygen sensor and flow meter. It adopts pressure swing absorbers(PSA) directly concentrate the medical oxygen from the air.

The machine takes the advantages of small in volume, light in weight, convenient in moving (as it has turning truckle), stable in performance, easy in operating, low in noise, which complies with requirements of medical device.

Fig 7-1 Working Frame of OC3D



The OC3D is divided into power module, MCU control module, Pressure detection module, Oxygen concentration detection module, alarm module, Compressor and fan drive module, Solenoid valve drive module, Display driver module, Work indication module, button detection module.

Power module: provide power supply for each system module;12V/3A power is supplied by the power board, MCP1702-5002E/M supplies 5.0V for oxygen concentration collection, L7805CV 5.0V is the system power, which form two 3.3V power supply through the two TLV70033DDCR , used to be compatible with the system and screen voltage.

MCU control module: MCU is to detect the status of pressure, oxygen concentration and buttons, and to control the drives of compressors, fans, solenoid valves, displays, and indicators as required

Pressure detection module: MCU collects the pressure value at a certain frequency through the AD. When the detected pressure exceeds the maximum limit and the minimum limit, the alarm signal is triggered and displayed on the screen.

Oxygen concentration detection module: MCU collects the oxygen concentration and the flow value at a certain frequency. When the detected oxygen concentration and the flow value exceeds the maximum limit and the minimum limit, the alarm signal is triggered and displayed on the screen.

Alarm module: If the device detects the alarm trigger signal in working status, such as high system pressure, low system pressure, low flow rate, the oxygen concentration is below 82% or below 60%, MCU will drive alarm circuit, to send sound alarm and light alarm. If the power supply is

interrupted in the running status of the device, electrical energy stored in the board card and the logic circuit will drive the buzzer to send the sound alarm.

Compressor and fan drive module: After receiving the signal of starting to make oxygen, the MCU turns on the electric relay and turns on the compressor, and the fan to work.

Solenoid valve drive module: After receiving the signal of starting to make oxygen, and after the compressor and the fan is opened ,then delay for a period of time, and then switch on the solenoid valve Display driver module: MCU drive display module to display the system running information, running total time etc. on the screen.

Work indication module: After MCU worked, the green light of drive is on; after making oxygen for 20min, if the oxygen concentration is less than 82% but not less than 60%, the yellow light will be lit, if the oxygen concentration is below 60%, then the red light will be lit; if system works abnormally and alarms, the red light will be lit.

Button detection module: When MCU detects a button input, the MCU performs key handling operations

Intended Use Statement:

CONTEC™ Oxygen Concentrator, OC3D, is intended to provide supplemental oxygen in a home, institutional environment. The device is only used for adult and prescription use only.

6. Substantially Equivalent (SE) Comparison

Table 7-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Device name	OC3D CONTEC™ Oxygen concentrator	RS-00500 GCE Zen-O™ Portable Oxygen Concentrator
Classification Name	Portable oxygen generator	Portable oxygen generator
Product Code	CAW	CAW
Regulation Number	CFR 868.5440	CFR 868.5440
Comparison Statement	**The proposed device has same classification information as the predicate device.**	
Intended Use	CONTEC™ Oxygen concentrator, OC3D, is intended to provide supplemental oxygen in a home, institutional, or travel environment.	The Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.
Patient Population	Adult	Adult
Single Patient, multi-use	Yes	Yes
Comparison Statement	**The proposed device has similar intended use as the predicate device.**	
Main Unit Technical Specifications		
Technology	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve
Dimensions	508(L) × 260(W) × 530(H) mm (20” L x 10.2” W x20.8” H)	6.6” H x 8.3” W x 12.3” L
Weight	21Kg(46.30lbs)	10.25 lbs
Oxygen Concentration	93%±3%	87% - 96%
Equivalent Flow Rates	0.5~3LPM	1-6 LPM, increments of 0.5 LPM 0.5 – 2 LPM, increments of 0.5 L (Continuous mode)
User Interface	Buttons LCD Display	Buttons LCD Display
Power supply	AC110V±10%, 60Hz±1Hz	100-240VAC, 50/60 Hz, 2.5A

		24VDC, 6.25A
Software	Embedded	Embedded
Acoustic Noise	≤55dB(A)	42 dB(A) at 2 LPM
Alarms	power failure high pressure low pressure low flowrate high temperature Low oxygen concentration Motor stall Compressor failure	Battery empty Low Pressure Motor communication No pulse Skipped Breaths High temp RAM failure Motor stall Compressor failure Fan failure Invalid Battery Low Flow Low Battery No Breath Detected uC timeput EEPROM failure EEPROM error
Status Indicators	Flowrates Alarms Power Failure indication	Flowrates Battery Condition Alarms History Log Diagnostics
Operating	Temperature: 10℃~40℃	Temperature: 5 ℃to 40℃

Environment	Relative humidity: ≤80% Atmospheric pressure: 860hPa~1060hPa Altitude: it can work normally from the altitude range 0 to 1900m,its efficiency is lower than 90% from the distance of 1900m to 4000m.	Relative humidity:5 – 93 % Altitude: 0-9000 ft(0-2743.2m)
Shipping / Storage Conditions	Temperature: -20°C~+60°C; Relative Humidity: ≤95%.	Temperature: -20 to 60oC, Keep Dry, Humidity: 0 - 93 % RH
Sterile	No	No
Single Use	No	No
Comparison Statement:	**The proposed device has the similar main unit specifications with the predicate device.**	
Applied Standards:		
Biocompatibility	ISO10993-5&ISO10993-10 4 VOC's less than ambient	4 VOC's less than ambient
Electrical Safety	IEC60601-1 IEC 60601-1-11	IEC60601-1 IEC 60601-1-11
EMC	IEC60601-1-2	IEC60601-1-2
Performance	ISO 80601-2-69	ISO 80601-2-69
alarm	IEC 60601-1-8	IEC 60601-1-8
Comparison Statement	**The proposed probe has same applied Standards with the predicate device.**	

7. Substantially Equivalent (SE) Conclusion

SE Analysis:

The subject device has same classification information, same intended use, same indication for use, similar product design, similar specification, similar applied Standards as predicate device.

The differences are included as followings:

Analysis 1：Although the Dimensions and Power supply specifications, Operating and Storage Environment Conditions of OC3D 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.

Analysis 2：The device and predicate device have difference in alarms，but they have same alarms relating to the basic function of safety and performance, such as pressure, flowrate, oxygen concentration, motor and compressor. Hence, there are no different questions of safety and effectiveness questions pertaining to alarms.

Analysis 3: The device and predicate device have difference in flow rate accuracy， but 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.

Analysis 4: The subject device and the predicate device have differences in Acoustic Noise, Alarms information displayed, Status Indicators. However, the proposed device meets the requirements of the standard ISO80601-2-69 and IEC60601-1-8. In addition, performance testing, human factors study, risk analysis has been conducted on the subject device. Hence, there are no different questions of safety and effectiveness questions pertaining to Performance of the subject device.

8. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

a. IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
b. IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
c. ISO 80601-2-69 First Edition 2014-07-15, Medical Electrical Equipment - Part 2-69: Particular Requirements For Basic Safety And Essential Performance Of Oxygen Concentrator Equipment
d. IEC 60601-1-8 Edition 2.1 2012-11, Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General

Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems.

e. IEC 60601-1-11 Edition 2.0 2015-01, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment .

f. ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.

g. ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity

h. Testing for Ozone concentration, TVOC, PM2.5, CO, NO_2, Criteria is Ozone concentration< 0.16mg/m^3, TVOC < 0.60mg/m^3, PM2.5< 35 μg/m^3, CO< 10 mg/m^3, NO_2<200 μg/m^3.

i. Human Factor study test was conducted by Contec Medical System Co., Ltd according to the Human Factor Study Protocol. This test required 15 US evaluators to perform a simulate operation of OC3D Oxygen concentrator, and then filled in the questionnaires after operation. The observer will document the duration when the evaluator can fulfill the task according to the pass/fail criteria.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

As detailed above, the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.