



March 23, 2018

DeVilbiss Healthcare, LLC  
Sandy Figueroa  
Manager, Regulatory Affairs  
100 DeVilbiss Drive  
Somerset, Pennsylvania 15501

Re: K172648

Trade/Device Name: Drive DeVilbiss iGo 2 Portable Oxygen Concentrator  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Portable Oxygen Generator  
Regulatory Class: Class II  
Product Code: CAW  
Dated: February 19, 2018  
Received: February 20, 2018

Dear Sandy Figueroa:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Michael J. Ryan -S

for 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

Enclosure

## Indications for Use

510(k) Number (if known)

K172648

Device Name

Drive DeVilbiss iGo2 Portable Oxygen Concentrator

Indications for Use (Describe)

The Drive DeVilbiss iGo2 Portable Oxygen Concentrator is indicated for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

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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## **Section 5.0 510(k) Summary**

### **Administrative Information and Device Identification**

Name and address of the manufacturer and sponsor of the 510(k) submission:	DeVilbiss Healthcare LLC 100 DeVilbiss Drive Somerset, PA 15501
Official contact person for all correspondence:	Betty Miller Regulatory/Compliance Manager Phone: 814-443-7606 Fax: 814-443-7575
Date Prepared:	March 22, 2018
Device Name:	Drive DeVilbiss iGo2 Portable Oxygen Concentrator
Proprietary name of new device:	Drive DeVilbiss iGo2 Portable Oxygen Concentrator
Common or usual name of the device:	Generator, Oxygen, Portable
DeVilbiss Model Number	125D, 125K, 125AA
Classification	Class II
Panel Code:	CAW
CFR Regulation Number:	21 CFR 868.5440
Primary Predicate Device Name and 510(k) number:	DeVilbiss iGo 306DS Portable Oxygen Concentrator (K081468)
Reference Device Name and 510(k) number:	Model 350G Gas Conserver (K090421)

### **Description of Device:**

The proposed Drive DeVilbiss iGo2 Portable Oxygen Concentrator (POC) is similar to the predicate devices, pressure-vacuum swing adsorption based on molecular sieve technology using two containers filled with molecular sieve (sieve beds). Ambient air is drawn into the concentrator via a piston style compressor and compressed into a single sieve bed. As pressure increases nitrogen is adsorbed and concentrated oxygen exits one end of the bed and is collected in a product tank. Simultaneously in the other sieve bed, nitrogen is desorbed as the pressure decreases to a vacuum and is exhausted into the atmosphere. Once the pressure or vacuum reaches a defined maximum a valve switches the compressor connections to the sieve beds. The sieve bed previously connected to the pressure head will be connected to vacuum. The oxygen collected in the product tank is then dispensed to the patient upon detecting a patient inhalation, much like an oxygen conserving device.

The proposed Drive DeVilbiss iGo2 POC provides pulse dose oxygen in the same manner as primary predicate device (DeVilbiss Model 306 POC, K081468). The “Smart Dose” feature has been added to the proposed device, which is substantially equivalent to the feature in the reference device (Model 350G gas

conserver, K090421). Smart Dose will automatically increase the patient's prescription setting by one if the system determines the patient has increased rate of breathing.

This device is intended for Adult and Pediatric patients with a bodyweight >10kg.

**Indication for Use:**

The Drive DeVilbiss iGo2 Portable Oxygen Concentrator is indicated for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

**Substantial Equivalence:**

The proposed (modified) Drive DeVilbiss iGo2 Portable Oxygen Concentrator has the following similarities to those which previously received 510(k) concurrence:

- Indications for Use Statement
- Operating Principle
- Incorporates similar materials, and
- Is manufactured and packaged using similar materials and processes.

Design and verification activities were performed on the proposed Drive DeVilbiss iGo2 Portable Oxygen Concentrator according to design requirements and risk analysis outputs. All bench tests confirmed that the predetermined acceptance criteria were met. This includes oxygen output and breathing detection.

**Comparison of Substantial Equivalence and Differences:**

Characteristics	Predicate Device DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468	Reference Device Model 350G Gas Conservor K090421	Subject Device	Nature of Change	Legally Marketed Product with same feature or specification
Item Description/ Method of Operation	<p>1-3 lpm continuous flow (1-6 pulse dose), pressure-Vacuum swing adsorption, oxygen concentrator based on molecular sieve technology. Ambient air is drawn into the concentrator via a piston style compressor. The air then passes through a series of filters that remove dust, bacteria, and other particulate. A poppet-style valve directs air into one of two sieve beds. Nitrogen is adsorbed in the bed as the pressure increases while oxygen flows through, thereby producing a highly enriched oxygen product. Simultaneously in the other bed, nitrogen is absorbed as the pressure decreases and is exhausted into the atmosphere. A momentary intermediate pneumatic sequence ties the beds together with the exhaust blocked for an enhanced nitrogen purge. The cycle continues providing a flow of oxygen to the patient. Oxygen is provided to the patient on a continuous or pulse-dose basis.</p>	<p>The Inspired Technologies 350G Gas Conservor is intended as a delivery device for medial-grade oxygen from high-pressure oxygen cylinders.</p>	<p>(1-5 pulse dose), pressure-Vacuum swing adsorption, oxygen concentrator based on molecular sieve technology. Ambient air is drawn into the concentrator via a piston style compressor. The air then passes through a series of filters that remove dust, bacteria, and other particulate. A valve directs air into one of two sieve beds. Nitrogen is adsorbed in the bed as the pressure increases while oxygen flows through, thereby producing a highly enriched oxygen product. Simultaneously in the other bed, nitrogen is absorbed as the pressure decreases and is exhausted into the atmosphere. A momentary intermediate pneumatic sequence ties the beds together with the exhaust blocked for an enhanced nitrogen purge. The cycle continues providing oxygen to the patient. Oxygen is provided to the patient on a pulse-dose basis.</p>	<p>Minor constructional differences. POC will be smaller and not support continuous flow.</p> <p>No different questions of safety or effectiveness.</p>	<p>DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468</p>
Target Population/ Indications for Use	<p>The Model 306 Portable Oxygen Concentrator is indicated for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.</p>	<p>This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder.</p>	<p>The Portable Oxygen Concentrator is indicated for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.</p>	<p>Same. Provides pulse oxygen to patient. No different questions of safety or effectiveness.</p>	<p>DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468</p>
Where Used/ Intended Use	<p>Oxygen concentrators are intended to provide supplemental oxygen to persons requiring low flow oxygen therapy. The patient typically receives the oxygen through a nasal cannula. The device delivers continuous oxygen or oxygen pulses during a patient's inhalation phase. The pulse flow provides over 87% oxygen concentration. It is used at a patient's home or for their portable needs outside the home and can also be used in institutions such as nursing homes or sub-acute care facilities. Oxygen concentrators are not considered life supporting nor life sustaining. The device has no contraindications.</p>	<p>The 350G Gas Conservor is intended to be used in the hospital, healthcare facilities, or home care environments.</p>	<p>Oxygen concentrators are intended to provide supplemental oxygen to persons requiring low flow oxygen therapy. The patient typically receives the oxygen through a nasal cannula. It is used at a patient's home or for their portable needs outside the home and can also be used in institutions such as nursing homes or sub-acute care facilities. Oxygen concentrators are not considered life supporting nor life sustaining. The device has no contraindications.</p>	<p>Same. No different questions of safety or effectiveness.</p>	<p>DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468</p>

Characteristics	Predicate Device DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468	Reference Device Model 350G Gas Conservor K090421	Subject Device	Nature of Change	Legally Marketed Product with same feature or specification
Operating Principle	Pressure-vacuum-swing adsorption / pressure controlled oxygen separation process	Integral high pressure regulator Dosing device and algorithm Valves	Pressure-vacuum-swing adsorption / pressure controlled oxygen separation process	Same as iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Standards Certification	IEC 60601-1 2nd Edition IEC 60601-1-1 IEC 60601-1-2 ISO 8359 ISO 14971 ISO 13485	FCC CFR47 Parts 15B and 18 Industry Canada BS EN 55011:2007 IEC 60601-1 IPX I	IEC 60601-1 3rd Edition IEC 60601-1-1 IEC 60601-1-2 ISO 80601-2-69 ISO 80601-2-67 ISO 14971 ISO 13485	New device conforms to newer revisions of standards. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Output Capacity and Delivery Modes	3 LPM maximum continuous flow. Continuous flow settings: 1 to 3.0 LPM in 0.5 LPM increments Pulse flow settings: 1.0 to 3.0 in 0.5 increments; 3.0 to 6.0 in 1.0 increments	16.0 cc/lpm x setting value( i.e. 16x 1=16, 16 x 2 =32 etc) at 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 5.0, and 6.0 Lpm flow settings Sport mode 1 is setting value + 16 cc Sport Mode 2 is setting value +32 cc/lpm	Pulse flow settings: 1.0 to 5.0 in 1.0 increments	Does not support Continuous flow.  Pulse mode like iGo 306DS but supports a smaller set of the patient population because of smaller bolus volume.  Supports Smart Dose (Sport Mode)	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468  Model 350G Gas Conservor K090421
Voltage Required	AC operation: 100-240 VAC, 50-60 Hz DC operation: 12-24 VDC	4 "AA" batteries	AC operation: 100-240 VAC, 50-60 Hz DC operation: 10 – 15 VDC	Minimal difference. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Dimensions	15"H x 12"W x 9"D Cube volume: 1620 cu. in.	6"H x 3.5"W x 4"D	9.6"H x 8.75"W x 3.6"D Cube volume: 302.4 cu. in.	Smaller more portable device than iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Weight	17.9 lbs, including battery, 19.9 lbs with lightweight cart	1.39 lbs	Less than 6 lbs, including a standard battery pack.	Lighter more portable device than iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
O2 Performance Specification	90% +/-3% at 1 lpm to 3 lpm at sea level	N/A – Uses bottled gas	87-94% at all settings	Same as iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Noise Level @ 2 lpm	40 dBA at pulse flow setting 3; 47 dBA overall maximum at 3 LPM continuous flow	N/A – Uses bottled gas	46 dBA at pulse flow setting 2	Louder than iGo 306DS but no different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Power Consumption	42 Watts at 1.0 LPM continuous flow 104 Watts at 3.0 LPM continuous flow 31 Watts at 1.0 pulse flow setting (20 BPM) 62 Watts at 6.0 pulse flow setting (20 BPM)		Approximately 30 Watts at setting of 2 (20 BPM)	Pulse dose efficiency is better. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468

Characteristics	Predicate Device DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468	Reference Device Model 350G Gas Conserver K090421	Subject Device	Nature of Change	Legally Marketed Product with same feature or specification
Patient Oxygen Outlet Pressure	5 psig	19-25 PSIG	15 psig	Higher pulsed output pressure than iGo but lower than 350G. Will deliver oxygen faster than iGo but there is no different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Filtration	Patient-maintainable gross particle filter	None	Gross particle filter	Same as iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Battery Run Time	Tested times: 4.1 hours at 1.0 LPM 1.7 hours at 3.0 LPM 5.8 hours at 1.0 LPM (10 BPM) 2.0 hours at 6.0 LPM (30 BPM)	NA	4.5 hours at a setting of 2 (20 BPM)	Same as iGo 306DS at equivalent pulse output. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Compressor Pressure Relief Valve	Pressure Relief valve	NA	Over-pressure protection achieved through software and electronic control.	No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Pneumatic Valve	Two Three way valves	NA	Two Three way valves	Off the shelf valves - No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Molecular Sieve Material	Zeochem lithium-based zeolite	NA	Zeochem lithium-based zeolite	Same as iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Flow Controller	Proportional control valve used for continuous flow and pulse flow	Pulse Valve	Pulse Valve only. Use software to regulate output.	Same as iGo 306DS.No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Insulation Class	IEC Class 1, Type BF	Not Published	IEC Class 2, Type BF	Improved required by ISO standard. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Water Ingress	IPX0 – bare unit IPX1 – Unit with battery	IPX1	IPX1 Or IPX22	Improved liquid ingress capability. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Hour meter	Mechanical Hour meter	None	Microprocessor or other nonvolatile memory.	Used for service and dealer. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468

Characteristics	Predicate Device DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468	Reference Device Model 350G Gas Conserver K090421	Subject Device	Nature of Change	Legally Marketed Product with same feature or specification
Oxygen Monitor	Ultrasonic oxygen and flow sensing device (FDA approved Re: K913392/B)	None	Ultrasonic oxygen and flow sensing device (FDA approved Re: K913392/B)	Same as iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Patient Alert Indications	Concentration <82% - yellow light  Concentration <75% - red light/beep  Blocked flow – blink green/beep  No breath detected in pulse flow mode – after 30 seconds, unit beeps/yellow no-breath- detected light; 1 minute after first beep, unit shifts automatically to continuous flow.  Low battery - yellow light on battery guage  Battery communication error (to main control PCB) – blink yellow light/beep  Patient indicator check at start-up	Low Battery Indicator :  Flashes red when batteries are low, & should be replaced. (Typically 8 hours remain)  Solid red when batteries are below usable range.	Concentration <86% - yellow light  Concentration <85% - yellow light/beep  Blocked flow – blink green/beep  No breath detected unit beeps/yellow no-breath- detected light.  Low battery - yellow light on battery gauge  Battery communication error (to main control PCB) – blink yellow light/beep  Patient indicator check at start-up	Same number of Alerts as iGo 306DS. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
Unit shutdown conditions	Battery shutdown or hot battery -no external power present – blinking red/steady tone.  Loss of external power – no charged battery present – flash green light; steady tone  “Service Required” – steady red light and audible tone (checksum error, battery communication error, bad OSD piezo data, OSD thermistor failure, high system pressure; motor controller communication error; purge valve failure)  High temperature measured in OSD – red light; audible tone; shut down  Long cycle time (indicates leaks, loss of compressor piston seal, etc.) – red light; audible tone; shut down	Unit does not pulse and patient switches to continuous flow.	Battery shutdown or hot battery -no external power present – blinking red/steady tone.  “Service Required” – steady red light and audible tone (System Leaks, checksum error, battery error, thermistor failure, bad system pressure; purge valve failure)  High temperature – red light; audible tone; shut down	No differences from iGo 306DS. Long Cycle time error covered under Service Required. If iGo2 has loss of external power with no battery the unit will not run. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468
User interfaces	Digital indications for operational status, battery status and alert indications. Push buttons for status changes on front panel.	Digital indications for operational status, battery status and alert indications. Push buttons for status changes on front panel.	LCD with indications for operational status, battery status and alert indications. Push buttons for status changes on front panel.	Same information will be displayed with either LCD or digital keypad overlay. No different questions of safety or effectiveness.	DeVilbiss iGo 306DS Portable Oxygen Concentrator – K081468

### Discussion of Substantial Equivalence and Differences:

The proposed (modified) Drive DeVilbiss iGo2 Portable Oxygen Concentrator is **identical** to the predicate device DeVilbiss iGo 306DS Portable Oxygen Concentrator (K081468) in the following characteristics:

- Indications for Use Statement
- Operating Principle
- Oxygen Performance
- Oxygen Monitoring capability
- Operating Temperature/ Humidity Range
- Operating atmospheric pressure range
- IEC 60601-1 Classification
  - Shock and Vibration
  - Storage Temperature Range

The proposed (modified) Drive DeVilbiss iGo2 Portable Oxygen Concentrator is **similar** to the predicate device Model 350G Gas Conserver K090421 with regard to the following characteristic:

- Smart Dose Feature (Called Sport Mode in predicate)

### Modifications made to the proposed Drive DeVilbiss iGo2 Portable Oxygen Concentrator:

#### **Delivery Mode and Pulse Volumes**

The DeVilbiss Model 306 POC supports continuous flow and pulse dose. The proposed Drive DeVilbiss iGo2 POC supports only pulse dose. The proposed Drive DeVilbiss iGo2 POC is designed to be small and light weight and therefore has smaller pulse volumes than the DeVilbiss Model 306 POC.

The proposed Drive DeVilbiss iGo2 POC will support a smaller set of patients. The oxygen delivery setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories.

This modification has no different questions of safety or effectiveness.

#### **Power Requirements**

Predicate device requires a larger power supply. This modification has no different questions of safety or effectiveness.

Both predicate and modified device battery options employ Lithium Ion Battery technology that complies with current US and international hazardous material shipping regulations. This modification has no different questions of safety or effectiveness.

#### **Sieve Material**

The predicate uses a different sieve material than the modified device. Both devices use a zeolite molecular sieve but they are different formulas. This modification has no different questions of safety or effectiveness.

## Smart Dose Feature

The proposed Drive DeVilbiss iGo2 POC implements a feature called “Smart Dose” feature that is equivalent to a feature implemented in the predicate device Model 350G Gas Conserver called “Sport Mode.” This modification has no different questions of safety or effectiveness.

### Performance Testing:

#### Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The proposed Drive DeVilbiss iGo2 Portable Oxygen Concentrator was designed and tested to demonstrate compliance with the applicable sections of the following standards:

1. AAMI / ANSI ES60601-1:2005/(R)2012 Ed 3.1 and A1:2012 Basic Safety and Essential Performance
2. AAMI / ANSI / IEC 60601–1–2:2014, Ed. 4.0
3. IEC 60601-1-8 Ed. 2.1 b.2012 Medical electrical equipment - Part 1-8
4. IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Home healthcare environment
5. ISO 80601-2-69:2014 Medial electrical equipment Oxygen Concentrator Equipment
6. ISO 80601-2-67:2014 Medical electrical equipment Oxygen Conserving Equipment
7. ISO 62304

#### Clinical Testing:

No clinical testing was necessary to demonstrate the substantial equivalence of the proposed Drive DeVilbiss iGo2 Portable Oxygen Concentrator. Patient simulation models were used for bench testing

### Statement of Substantial Equivalence:

Comparing the proposed (modified) Drive DeVilbiss iGo2 Portable Oxygen Concentrator with the predicate device (DeVilbiss iGo 306DS Portable Oxygen Concentrator, K081468) and reference device (Model 350G Gas Conserver, K090421), we believe the device, as tested, to be substantially equivalent to the predicate device in terms of meeting performance criteria and functioning as intended.

### Conclusion:

Given the similarity between the proposed (modified) Drive DeVilbiss iGo2 Portable Oxygen Concentrator with the predicate device, we believe the device, as changed, does not raise different questions of safety and effectiveness and is substantially equivalent to the predicate device previously cleared.