



March 26, 2026

Devilbiss Healthcare, LLC  
Susan Scott  
Senior Director, Regulatory Affairs  
100 Devilbiss Dr.  
Somerset, Pennsylvania 15501

Re: K253549

Trade/Device Name: DeVilbiss 5 Liter Oxygen Concentrator (555)  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Portable Oxygen Generator  
Regulatory Class: Class II  
Product Code: CAW  
Dated: February 18, 2026  
Received: February 18, 2026

Dear Susan Scott:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combo-products/guidance-regulatory-information/postmarketing-safety-reporting-combo-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Bradley Q. Quinn -S**

Bradley Quinn  
Assistant Director  
DHT1C: Division of Anesthesia,  
Respiratory, and Sleep Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K253549

Device Name

DeVilbiss 5 Liter Oxygen Concentrator (555)

Indications for Use (Describe)

The DeVilbiss 5 Liter (555) Oxygen Concentrator is intended to provide supplemental oxygen to adult patients requiring oxygen therapy. The device may be used in the home or an institutional setting. The device is not intended to be life sustaining or life supporting.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator 510(k) Summary

## 1. SUBMITTER INFORMATION

Applicant: DeVilbiss Healthcare LLC  
Contact: Susan Scott  
Phone: (801) 931-1050  
Email: sscott@drivemedical.com  
Address: 100 DeVilbiss Dr  
Somerset, PA 15501, USA

## 2. CORRESPONDENT INFORMATION

Contact: Susan Scott  
Title: Senior Director, Regulatory Affairs  
Firm: DeVilbiss Healthcare LLC

## 3. DATE PREPARED: NOVEMBER 13, 2025

## 4. DEVICE INFORMATION

Device Name: DeVilbiss 5 Liter (555) Oxygen Concentrator  
Common Name: Portable oxygen generator  
Regulation Number: 868.5440  
Regulation Name: Generator, Oxygen, Portable  
Product Code: CAW  
Regulatory Class: Class II

## 5. PREDICATE DEVICE INFORMATION

Device Name: JUMAO Oxygen Concentrator  
Common Name: Portable oxygen generator  
510(k) Number: K230969  
Manufacturer: Jiangsu Jumao X-Care Medical Equipment Co., Ltd.

The predicate device has not been subject to a design related recall.

## 6. DEVICE DESCRIPTION

The DeVilbiss 5-Liter (555) Oxygen Concentrator (hereafter referred to as “555”) is a portable device that produces an oxygen enriched gas mixture by drawing in room air and extracting nitrogen through a pressure swing adsorption process, allowing oxygen to be delivered at a range of prescribed flows to patients in need of supplemental oxygen.

**DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator  
510(k) Summary**

**7. INDICATIONS FOR USE**

The DeVilbiss 5 Liter (555) Oxygen Concentrator is intended to provide supplemental oxygen to adult patients requiring oxygen therapy. The device may be used in the home or an institutional setting. The device is not intended to be life sustaining or life supporting.

## DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator 510(k) Summary

### 8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

**Table 1: Device Comparison Table**

Characteristic	Predicate Device: JUMAO Portable Oxygen Concentrator (K230969)	Subject Device: DeVilbiss 5 Liter (555) Oxygen Concentrator	Comparison
Product Code	CAW (generator, oxygen, portable)	CAW (generator, oxygen, portable)	Same
Indications for Use Statement	The JUMAO Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.	The DeVilbiss 555 oxygen concentrator is intended to provide supplemental oxygen to adult patients requiring oxygen therapy. The device may be used in the home or an institutional setting. The device is not intended to be life sustaining or life supporting.	Equivalent. The differences do not result in a new intended use.
Intended patient population	The device is intended for use in adults.	The device is intended for use in adults.	Same
Proprietary name	Oxygen Concentrator	5 Liter (555) Oxygen Concentrator	Same
Structure and main components	JMC5A Ni oxygen concentrator is made up of mainframe and flowmeter. The front panel of the device contains the controls and indicators. These include a standard barb fitting for attaching the oxygen tubing, the adjustable flow meter, a power light indicator, an elapsed time meter, and a standard on/off rocker type power switch.	The DeVilbiss 555 oxygen concentrator consists of a unit housing that includes a compressor and sieve beds. The device includes a control panel that provides Flow settings and alarm displays. A standard barb fitting provides for connection to a nasal cannula. The front panel includes a rocker style on/off power switch.	Equivalent.
Filters	Cabinet, out HEPA, compressor inlet	Intake HEPA, Internal Compressor, Final HEPA	Same
Material of main components	Materials demonstrated to be biocompatible for gas-pathway contact	Materials demonstrated to be biocompatible for gas-pathway contact	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Technology	Pressure Swing Adsorption with a Molecular Sieve	Pressure Swing Adsorption with a Molecular Sieve	Same

## DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator 510(k) Summary

Characteristic	Predicate Device: JUMAO Portable Oxygen Concentrator (K230969)	Subject Device: DeVilbiss 5 Liter (555) Oxygen Concentrator	Comparison
Power Requirements	AC120V, 60Hz; Current: 3.5A; Power: 450VA	120 V~, 60 Hz, 2.6 A Max	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Oxygen concentration	93%±3% at 0.5 to 5L/min (after turning on 5 minutes)	87% - 96% at 0.5-5 LPM	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Oxygen flow	Continuous oxygen flow, adjustable 0.5~5L/min	Continuous oxygen flow, adjustable 0.5 to 5 LPM	Same
Outlet pressure	38kP a± 5kPa	8.5 PSIG regulated oxygen outlet pressure	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Noise Level	Sound level: ≤ 50.5dB (A); Acoustic power level: 58.5dB (A)	A-weighted sound pressure level: <46 dBA Sound power level @ 5 LPM: <56 dBA	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Weight	16.1kg	30 lbs (13.6kg)	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Dimensions	330×260×540(mm)	18.4" H x 14.6" W x 9.9" D (46.6 x 37.0 x 25.0 cm)	Equivalent The technological differences do not raise a different question of safety or effectiveness.

## DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator 510(k) Summary

Characteristic	Predicate Device: JUMAO Portable Oxygen Concentrator (K230969)	Subject Device: DeVilbiss 5 Liter (555) Oxygen Concentrator	Comparison
Electric classification	Class II, Type BF	Class II, Type BF	Same
Alarm	<ul style="list-style-type: none"> <li>• Start-up fail alarm</li> <li>• Low oxygen concentration alarm</li> <li>• Power supply failure alarm</li> <li>• Pressure failure alarm: <ul style="list-style-type: none"> <li>○ Outlet block, oxygen flowrate below 0.6 Lpm;</li> <li>○ Compressor stop</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Power supply failure</li> <li>• Low O2 concentration (start up period over)</li> <li>• Malfunction – O2 gas temperature</li> <li>• Malfunction – Obstruction of gas pathways, low flow</li> <li>• Malfunction – Corrupted settings</li> <li>• Malfunction – Non-recoverable valve error</li> <li>• Malfunction – O2 oxygen sensor communication failure</li> <li>• High flow</li> <li>• Malfunction – Fan not running</li> <li>• Startup period</li> </ul>	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Mode of operation	Continuous duty	Continuous duty	Same
Normal operating ambient	Temperature range: 5°C~40°C (41°F~104°F) Relative humidity: ≤80% Atmospheric pressure: 86kPa~106kPa (12.47psi~15.37psi) 1828 meter (5997 feet) height above sea level	Temperature range: 41°F (5°C) to 95°F (35°C) Humidity Range: 15% to 90%, non-condensing Atmospheric pressure: 1013 hPa to 715 hPa 0-3000 m (sea level-9840 ft) Across the voltage range: No degradation of performance	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Storage and transport ambient	Temperature Range: 0°C~+55°C (32°F~+131°F) Relative Humidity Range: 10%~90% Atmospheric pressure: 70kPa~106kPa (10.2psi~15.37psi)	Temperature Range: -13°F (-25°C) to 158°F (70°C) Humidity Range: 15% to 90%, non-condensing	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Software control	Yes	Yes	Same
Patient interface style	Visual, direct contact type patient interface	Visual, direct contact type patient interface	Same

# DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator 510(k) Summary

## 9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

### **Biocompatibility Testing**

Biocompatibility testing to the following standards was conducted:

- ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 10993-17:2023, Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
- ISO 16000-3:2022, Indoor air — Part 3: Determination of formaldehyde and other carbonyl compounds in indoor and test chamber air — Active sampling method
- ISO 16000-6:2021, Indoor air — Part 6: Determination of organic compounds (VVOC, VOC, SVOC) in indoor and test chamber air by active sampling on sorbent tubes, thermal desorption and gas chromatography using MS or MS FID
- ISO 80601-2-69: 2020, Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

### **Electrical Safety**

Electrical safety testing to the following standard was conducted:

- ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

### **Electromagnetic Compatibility (EMC)**

EMC testing to the following standard was conducted:

- IEC 60601-1-2:2020 (consolidated version), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

### **Software**

Software verification and validation was performed, and it was demonstrated that the software performs as intended in accordance with the FDA Guidance for the Content of Premarket Submissions for Device Software Functions

### **Performance Testing**

Performance testing to the following standards was conducted:

## **DeVilbiss Healthcare LLC: DeVilbiss 5 Liter (555) Oxygen Concentrator 510(k) Summary**

- ISO 80601-2-69:2020 Particular requirements for the basic safety and essential performance of oxygen concentrator equipment.
- IEC 60601-1-8:2020 (consolidated version), 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
- IEC 60601-1-11:2020 (consolidated version), 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
- ISTA 3A:2018, Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
- IEC 60601-1-6:2020 (consolidated edition), Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ANSI/AAMI/IEC 62366-1:2020 (consolidated edition), Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- IEC 62304:2015 (consolidated edition), Medical device software - Software life cycle processes

### **Conclusion**

The results of the performance testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.