December 9, 2025

DeVilbiss Healthcare LLC
Susan Scott
SVP, Quality and Regulatory
100 DeVilbiss Dr
Somerset, Pennsylvania 15501

Re: K250805
Trade/Device Name: DeVilbiss PulmO2 10-Liter Oxygen Concentrator (1060AW)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 3, 2025
Received: November 3, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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/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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JAMES J. LEE -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250805

Device Name

DeVilbiss PulmO2 10-Liter Oxygen Concentrator (1060AW)

Indications for Use *(Describe)*

The Devilbiss PulmO2 10-Liter Oxygen Concentrator is intended to provide supplemental oxygen to adult and pediatric patients >10kg 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.

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DeVilbiss Healthcare LLC: DeVilbiss PulmO2 10-Liter 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
Firm:	DeVilbiss Healthcare LLC

3. DATE PREPARED: OCTOBER 30, 2025

4. DEVICE INFORMATION

Device Name:	DeVilbiss PulmO2 10-Liter 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 PulmO2 10-Liter Oxygen Concentrator is a 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. The device is housed in a green cabinet.

7. INDICATIONS FOR USE

The PulmO2 10 Liter Oxygen Concentrator is intended to provide supplemental oxygen to adult and pediatric patients > 10 kg 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.

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 PulmO2 10-Liter (1060AW) 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 PulmO2 10 Liter Oxygen Concentrator is intended to provide supplemental oxygen to adult and pediatric patients > 10 kg 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 adult and pediatric patients > 10 kg requiring oxygen therapy.	Similar Note in the history of cleared indications for use for oxygen concentrators, the specific patient population is not identified beyond patients needing supplemental O2.
Proprietary name	Oxygen Concentrator	Devilbiss PulmO2 10-Liter (1060AW) 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 PulmO2 10-Liter (1060AW) 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.

DeVilbiss Healthcare LLC: DeVilbiss PulmO2 10-Liter Oxygen Concentrator
510(k) Summary

Characteristic	**Predicate Device:** **JUMAO Portable Oxygen Concentrator (K230969)**	**Subject Device:** **DeVilbiss PulmO2 10-Liter (1060AW) Oxygen Concentrator**	**Comparison**
Technology	Pressure Swing Adsorption with a Molecular Sieve	Pressure Swing Adsorption with a Molecular Sieve	Same
Power Requirements	AC120V, 60Hz; Current: 3.5A; Power: 450VA	100 – 240 VAC, 50/60 Hz 3.2 Amp	Equivalent The 1060 operates over the entire range due to the incorporation of a universal power supply and a DC compressor. The predicate device uses an AC compressor and only operates at a specific voltage. 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 1-10 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 1 to 10 LPM	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Outlet pressure	38kPa± 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 @ 3 LPM & @ 10 LPM < 60 dBA Sound Power Level @ 3 LPM & @ 10 LPM < 70 dBA	Equivalent The technological differences do not raise a different question of safety or effectiveness.

DeVilbiss Healthcare LLC: DeVilbiss PulmO2 10-Liter Oxygen Concentrator
510(k) Summary

Characteristic	Predicate Device: JUMAO Portable Oxygen Concentrator (K230969)	Subject Device: DeVilbiss PulmO2 10-Liter (1060AW) Oxygen Concentrator	Comparison
Weight	16.1kg	55.5 lbs (25.2kg)	Equivalent The additional weight is attributable to the increased capacity of 10 lpm compared to the 5 lpm capacity of the predicate. The technological differences do not raise a different question of safety or effectiveness.
Dimensions	330×260×540(mm)	27.75" H x 16" W x 14" D (70.5 cm H x 40.6 cm W x 35.6 cm D)	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Electric classification	Class II, Type BF	Class II, Type BF	Same

Alarms	• Start-up fail alarm
	• Low oxygen concentration alarm
	• Power supply failure alarm
	• Pressure failure alarm:
	  o Outlet block, oxygen flowrate below 0.6 Lpm;
	  o Compressor stop
		• Power supply failure
		• Low O2 concentration (start up period over)
		• Malfunction – high O2 gas temperature or high enclosure temperature
		• Malfunction – Obstruction of gas pathways, low flow
		• Malfunction – Corrupted settings
		• Malfunction – Non-recoverable valve error
		• Malfunction – O2 oxygen sensor communication failure
		• High flow
		• Malfunction – Fan not running
		• Malfunction – motor failure
		• Malfunction – over pressure
		• Malfunction – low pressure
		• Startup period
			Equivalent
			The technological differences do not raise a different question of safety or effectiveness.

DeVilbiss Healthcare LLC: DeVilbiss PulmO2 10-Liter Oxygen Concentrator
510(k) Summary

Characteristic	**Predicate Device:** **JUMAO Portable Oxygen Concentrator (K230969)**	**Subject Device:** **DeVilbiss PulmO2 10-Liter (1060AW) Oxygen Concentrator**	**Comparison**
Mode of operation	Continuous duty	Continuous duty	Same
Normal operating ambient	Temperature range: 5℃～40℃ (41℉～104℉) 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 104˚F (40˚C) Humidity Range: 15% to 95%, non-condensing Atmospheric pressure: 1013 hPa to 795 hPa 0-2000 m (0-6562 ft)	Equivalent The technological differences do not raise a different question of safety or effectiveness.
Storage and transport ambient	Temperature Range: 0℃～+55℃ (32℉～+131℉) 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 95%, 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

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:

- 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.