

**K250805 DeVilbiss PulmO2 10-Liter Oxygen Concentrator
(1060AW)**Dec 9, 2025
267 days to decisionK250805 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k250805/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Generator, Oxygen, Portable (CAW) |
| Date received | Mar 17, 2025 |
| Decision date | Dec 9, 2025 |
| Days to decision | 267 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Devilbiss Healthcare, LLC |
| Location | Somerset, PA, US |
| Contact | Christy Foreman |
| 510(k) history | 7 submissions · 7 cleared · 2011-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250805/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026