

K252965 Oxygen Concentrator (OX-5A, OX-5C)May 29, 2026
254 days to decisionK252965 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k252965/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Generator, Oxygen, Portable (CAW) |
| Date received | Sep 17, 2025 |
| Decision date | May 29, 2026 |
| Days to decision | 254 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Oxytek Medical Technology Co., Ltd. |
| Location | Chencun Town, Shunde District, Foshan, CN |
| Contact | Jenny Liu |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Share Info (Guangzhou) Medical Consultant , Ltd. |
| Contact | Cassie Lee |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252965/> 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 June 18, 2026